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Innovations in Lumbar Spinal Fusion Surgery

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By

Kevin J McNamara

Matthew J Skladany

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Approved:

Professor Yitzak Mendelson

Professor Chickery J Kasouf

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Abstract

The research in this document examines recent innovations in lumbar spinal fusion. Particular emphasis is made on laparoscopic spinal fusion techniques and interbody fixation devices. After doing extensive research, conducting interviews with surgeons and nurses, viewing a surgery, and distributing a questionnaire to postoperative spinal fusion patients, we formulated a patient brochure. At the time of this research, no patient brochures existed that incorporated these recent techniques in treating spinal fusion.

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Chapter 1: Introduction

Following the success of laparoscopic gall bladder removal there has been a tremendous growth in minimally invasive surgical techniques, including many abdominal procedures and now laparoscopic approaches to the lumbar spine. A laparoscopic approach to spinal surgery appears to be a logical step in expanding the minimally invasive approach to surgery. Early reports on this procedure boast many of the standard benefits associated with laparoscopic techniques, such as: decreased surgical time, less tissue trauma, and faster recovery/rehabilitation.

Minimal invasive surgery is a very powerful technique that can greatly reduce tissue trauma and provide the patient with a much faster recovery, than traditional surgical techniques. We postulate that in order for the benefits of minimal invasive spinal surgery to reach its full potential, patients need to be educated about the details surrounding these new procedures.

The goal of this project was to produce a brochure that will tell the patient everything he or she needs to know, so that they can feel comfortable and confident with the surgery they are about to face. This brochure will help patients determine what procedure is really right for them, what they should expect from their doctor and what is expected from them as patients, so the recovery process can go as smoothly as possible. In order to give to the patient an understanding of the procedure, the following topics were addressed:

1. A brief physiological description of the spine, along with the diseases and disorders that effect the vertebrae.

2. A description of different surgical techniques, explaining how each is performed and what conditions it is intended to treat.
3. Current technological advances in treating patients with back problems.
4. A description of minimal invasive spinal surgery.
5. Pre and post-operative guidelines that optimize the results of the procedure, and provide the quickest recovery.
6. The personal factors that each individual undertakes when making decisions about a new innovation

The most important task we are faced with is to communicate effectively to patients, informing them about their condition, explaining the most advanced techniques for treating their symptoms, and describing the results they can expect. We conducted interviews with doctors and nurses at the University of Massachusetts Memorial Hospital (UMMH), and observed a minimal invasive spinal fusion. Gaining further insight into the applications of the most recent technological advances and how they affect the patient. To obtain qualitative information from the perspective of the patient, we administered a questionnaire to patients. The questionnaire was anonymous and was given to patients returning to the orthopedic and neurosurgery clinics on their first postoperative follow-up visit.

The final product of this research took the form of a brochure. The beneficiaries of this information will be patients of all ages who have severe spinal problems, requiring lumbar spinal fusion.

Informing the patient is our number one priority with this brochure. Surgery can be a very traumatic and stressful experience for the patient. Our project is aimed at eliminating this stress as much as possible. A more knowledgeable patient, will be a more confident patient. He or she will cooperate with and understand the doctors' orders, or will be able to question their doctors' methods when they feel that their care is not good enough. Spinal fusion is not a "magic pill", that instantaneously relieves back pain, the patient has to make healthy back habits a part of their every day life. We hope that the more each patient can understand their treatment, the more active a role they can play in their recovery and get them back to a more active life style.

Chapter 2

Overview

Low back pain disables 5.4 million Americans and costs at least $16 billion annually to treat. Of these, only 5% to 10% require surgical intervention[3]. Most cases of acute low back pain resolve without the need for a detailed diagnosis or disease-specific treatment. However, in the medical history of low back pain, no conservative treatments have permanently affected the course of chronic low back pain. Thus, when conservative treatment fails to relieve a clearly identifiable and surgically treatable cause of lumbar pain, surgery may be beneficial.

Simply stated patients want relief of pain. Physicians need to make accurate diagnoses and provide appropriate treatment. Insurers demand a reduction in cost of care. Put more simply; all parties desire safe, effective, and efficient management of the problem. Until very recently these desires were largely unfulfilled; but the situation is changing. Until recently trying to identify the cause of low back pain has eluded doctors. Now with improvements in diagnostic equipment, such as MRI and discography, the cause of lower back pain can be identified in most individuals. However, correct management of these conditions remains elusive and controversial.

2.1 Anatomy of the Spine

In order for the patient to understand why they may need spinal surgery and how to protect their backs after surgery, they need to learn about the spine and how it works.

The spine is a column consisting of 33 vertebrae: 7 cervical (neck C1,C2-C7), 12 thoracic (upper back T1-T12), 5 lumbar (lower back L1-L5), 5 sacral, and 4 coccygeal (Fig 1). By adulthood, the 5 sacral vertebrae fuse to form one bone, and the 4 coccygeal vertebrae fuse to form one bone. The vertebral column is composed of four curves; from top to bottom, the cervical region, the thoracic region, the lumbar region, and the sacral region (Fig.1). These curves are normally kept in a balanced position by strong, flexible muscles, but because of injury or other degenerative conditions, these for curves are thrown into an unbalanced state.

Each of these four regions is made up of vertebrae, and vertebral discs that separate each vertebra[17]. Vertebral discs are composed of a tough outer layer of cartilage called the annulus fibrosis and a soft inner layer of cartilage called the nucleus pulposus, which together act as shock absorbers to adjacent vertebrae (Fig. 2).

The spine has 23 intervertebral disk joints and 46 posterior facet joints (joint of vertebra), all of which are subject to stresses and strains in holding the body upright, and moving it about. The spinal cord passes through the spinal canal formed by the vertebral arch (lamina), and the nerve roots leading to the legs, branch out from the spinal cord passing through vertebral spaces called foramen (Fig. 3). [18]

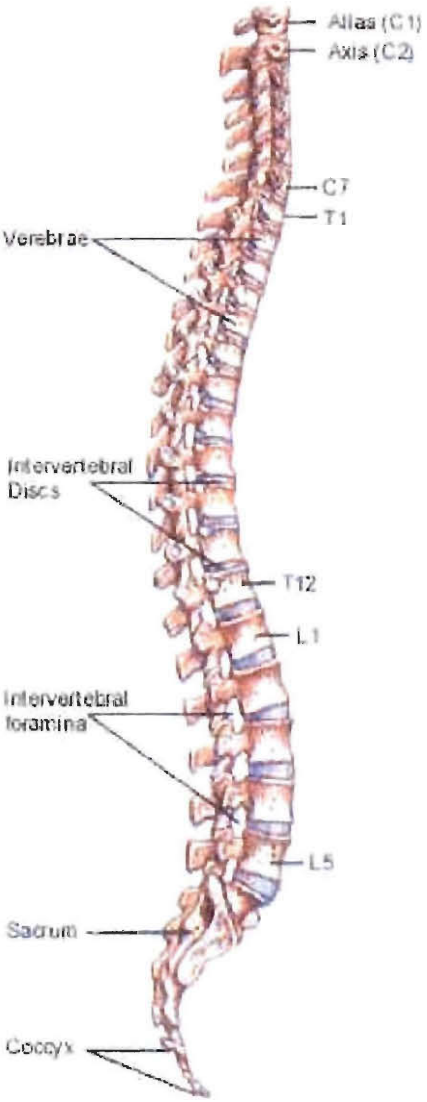


Figure 2-1
Curves and Anatomy
of the Spine

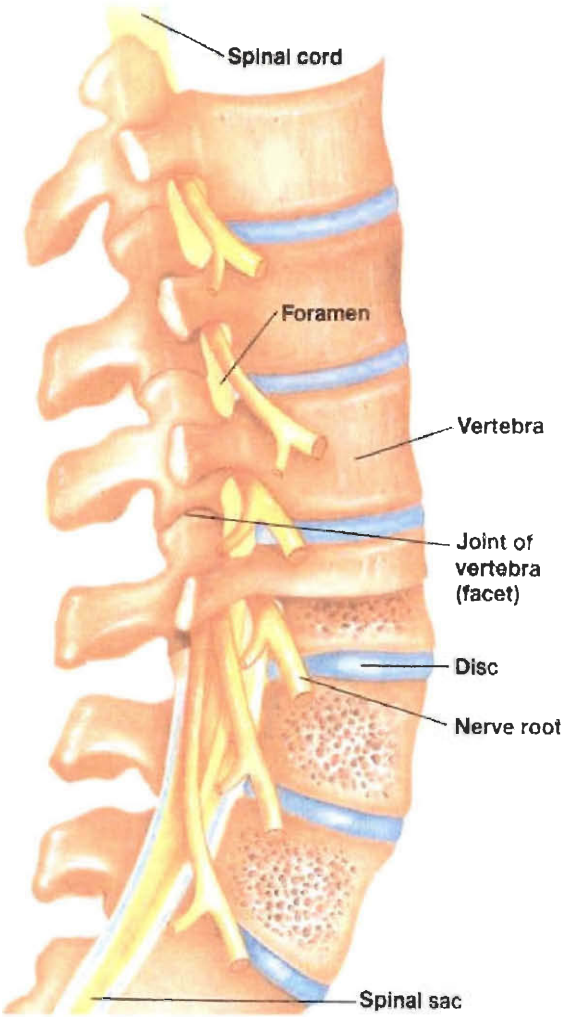


Figure 2-2
Closeup of Spine

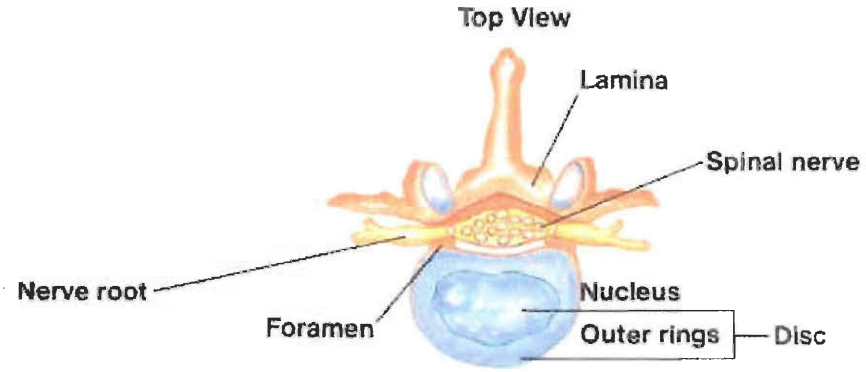


Figure 2- 3
Closeup of vertebrae

The vertebral column can be flexed, extended, abducted, adducted, and rotated. Thus, requiring strong, flexible muscles. The major muscles of spine are: rectus abdominus, erector spinae, and quadratus lumborum muscles. The muscle that flexes the vertebral column, the rectus abdominus, is a paired strap-like muscle of the anterior abdominal wall. The opposing extensor muscles (located on the posterior side of the vertebral column) must be stronger than the flexors because extension (such as lifting an object) is in opposition to gravity.

The erector spinae muscles constitute a massive superficial group that extends from the sacrum to the skull. It actually consists of three groups of muscles: the iliocostalis, longissimus, and spinalis muscles (Fig 4).

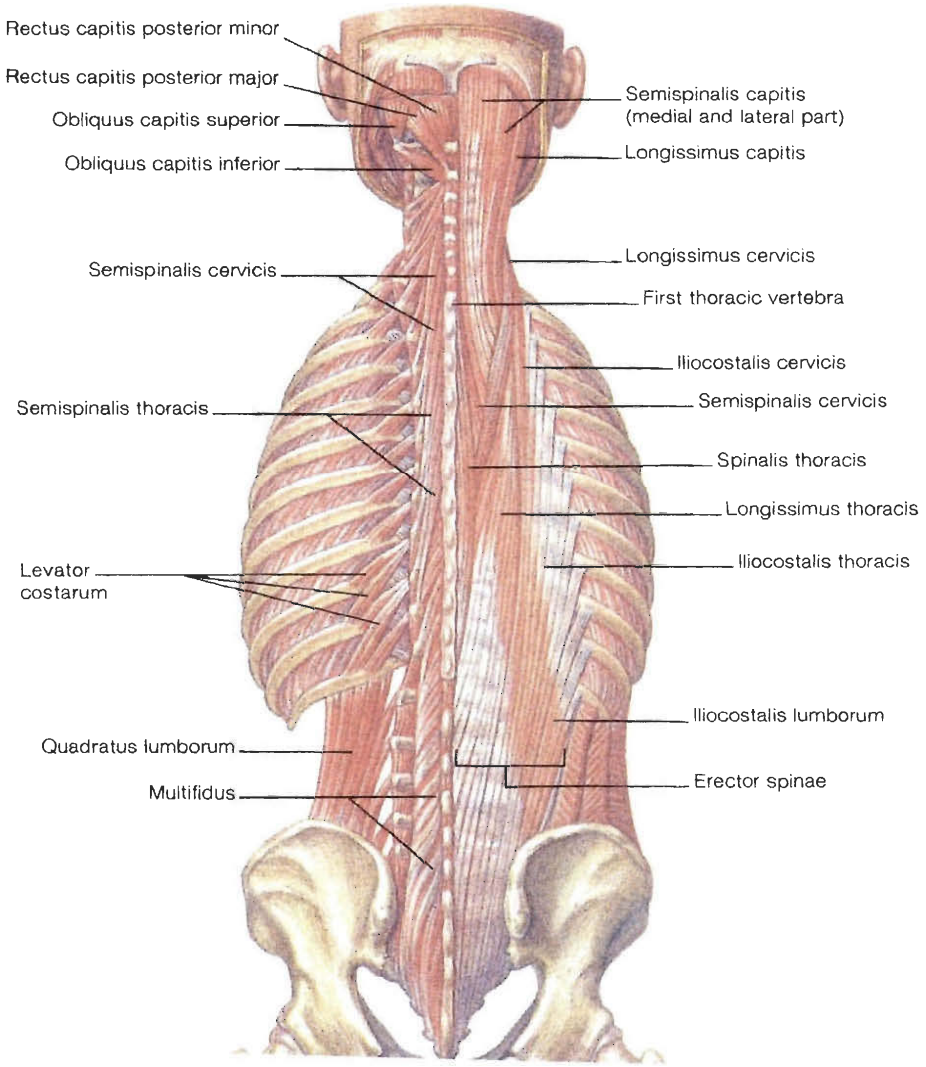


Figure 2-4
Musculature of the Spine

The iliocostalis is the most lateral group, the longissimus is intermediate in position, and the spinalis, in medial position, is in contact with the spinous processes of the vertebrae. The erector spinae muscles laterally flex the vertebral column and are strong extensors. The deep quadratus lumborum muscle originates on the iliac crest and lower three lumbar vertebrae. It inserts on the transverse processes of the first four lumbar vertebrae and the inferior margin of the twelfth rib. When the right and left quadratus lumborum muscles contract together, the vertebral column in the lumbar region extends.[19] (Fig. 2-5)

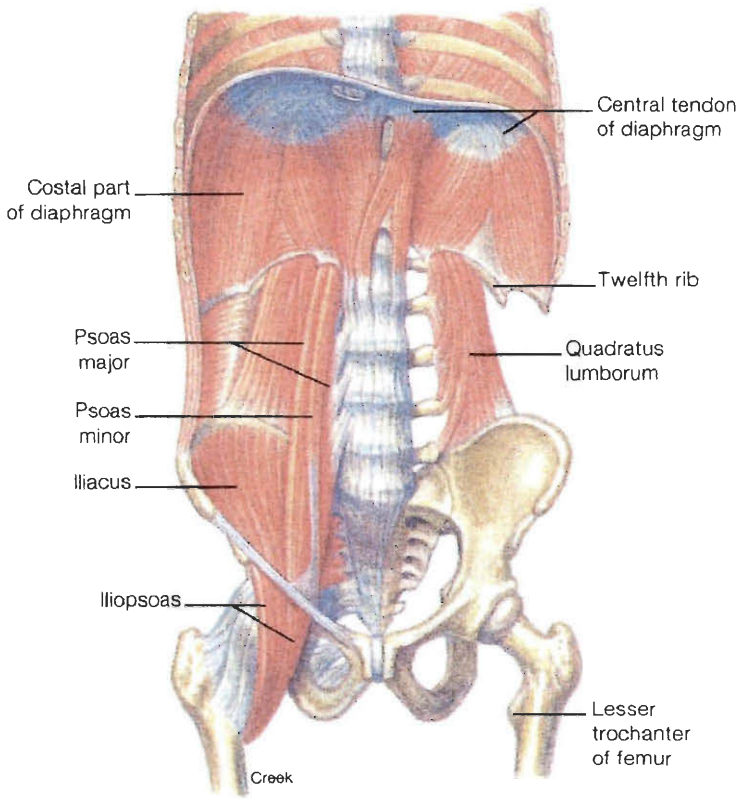


Figure 2-5
Anatomy and musculature

When these curves are in their normal alignment, the body is in a balanced position. Body weight is evenly distributed throughout the vertebrae and disks, so the body has minimal chance to strain and injury. However, when injury, natural aging process, and other degenerative conditions occur, some spinal problems can cause discs or bones to press on the roots of the spinal nerves, causing pain and various other symptoms. Since, this brochure is going to address lumbar spinal fusion we will be concentrating on the first level of the sacral region (S1), to the last lumbar vertebral level (L5) (Fig. 1). This area is typically the region of lumbar spinal fusion.

2.2 Disorders of the Spine

2.2.1 Degenerative Disease of the Spine

Evidence now suggests that degenerative disc disease is the primary source of chronic low back pain.[36, 32, 39] Degenerative disc disease involves a narrowing of the vertebral disc space and a thickening of the surrounding ligaments, which in turn narrows the spaces (foramen) through which the spinal nerve roots travel. Impingement of the nerve roots in the lumbosacral region is thought to be one cause of patient discomfort and pain in their backs and legs. Some common problems that arise in degenerative disc disease are:

1. Herniated nucleus pulposus (HNP), involves degeneration and dehydration of the cartilage composing the nucleus and the annulus, which act as shock absorbers for the vertebral discs. As the disk loses its resiliency, a strong force exerted on it can cause a slippage of the nucleus through the annulus, resulting in compression of the vertebrae.
2. Spinal stenosis, is a narrowing of the intervertebral foramina (spaces in the vertebrae where the spinal nerves pass) creating pressure on the nerve roots, along with neurologic symptoms and pain.
3. Degenerative and rheumatiod involvement of the hyaline articular surfaces of the facet joints results in pain, instability, and limited motion. This condition is particularly troublesome in the cervical spine.

The diagnosis of herniated disk is usually made on the basis of medical history and physical examination. A history of low back pain relieved by recumbency and aggravated by flexion of the trunk, coughing, or sneezing is typical. The patient will often complain of sciatic pain radiating down the leg. After the initial injury, some persons will have sciatic pain but no pain in their back. Straight leg raising with the hip flexed and the knee extended will produce sciatic pain. Neurologic signs and symptoms help in determining the level of the disk involved, since sensory and motor changes depend on nerve root involved. The most common sites of lumbar herniation are L3-L4, L4-L5, and L5-S1[12, 23].

Compression of nerve roots from other causes (such as, stenosis or vertebral instability) will also cause neurologic signs and symptoms relative to the level of the nerve root(s) involved. Signs and symptoms may include:

1. Numbness, tingling, and/or decreased motion in extremities
2. Pain
3. Weakness of one or more extremities
4. Muscle wasting in one or more extremities
5. Partial or complete loss of bowel and bladder control

Diagnostic tests to determine defects of the spine include x-ray, myelography, and MRI.

As a rule of thumb, patients should undergo a minimum of 4 months of aggressive physical rehabilitation before surgery is considered. Conservative treatment techniques such as rest, heat, medications (such as, analgesics, anti-inflammatory agents, or muscle relaxants), bracing and physical therapy are commonly used for degenerative spine disorders[23]. However, when non-surgical techniques do not provide relief from the symptoms of lower back pain, vertebral fusion is a surgical alternative.

Surgical interventions are designed to relieve pressure on (decompress) nerve roots and to stabilize the spine, which can be achieved with fusion of two or more vertebrae. Common indications for fusion are persistent back or buttock pain that occurs when the spine is loaded and goes away when the spine is no longer loaded. Pain arising only when the back is supporting weight is commonly referred to as mechanical back pain.

2.2.2 Scoliosis

Lateral deviation of the spine from the midline is known as scoliosis. The classifications of scoliosis are as follows:

1. Congenital – present at birth
2. Acquired – not present at birth, but develops at a later time
3. Functional (postural or nonstructural) – develops from temporary postural influences; easily correctable.
4. Idiopathic- most common type, usually develops in adolescence
5. Structural – changes in structure of spine from various causes
6. Paralytic – develops following neurologic disease such as poliomyelitis

Scoliosis may be present in both children and adults. Screening programs for school age children are effective in identifying early indications of scoliosis. Attention to good posture may be effective in preventing the disorder in both children and adult's.

Scoliosis may develop in localized areas of the spinal column or involve the whole spinal column (Fig 2-6). Curves may be S-shaped or C-shaped. The degree of rotation of the curve is important, since it determines the amount of impingement on the

rib cage. Significant cardiac and pulmonary restrictions may be imposed by curves with a large degree of rotation.

Early or postural scoliosis may be corrected with postural exercise or exercise combined with traction. In scoliosis where the curve is flexible, less than 40 degree, bracing in combination with exercise may be sufficient to correct the deformity. Corrective surgery is performed when the curve exceeds 40 degrees and/or bracing has failed. Surgery entails realignment of the vertebrae and fusion[23].

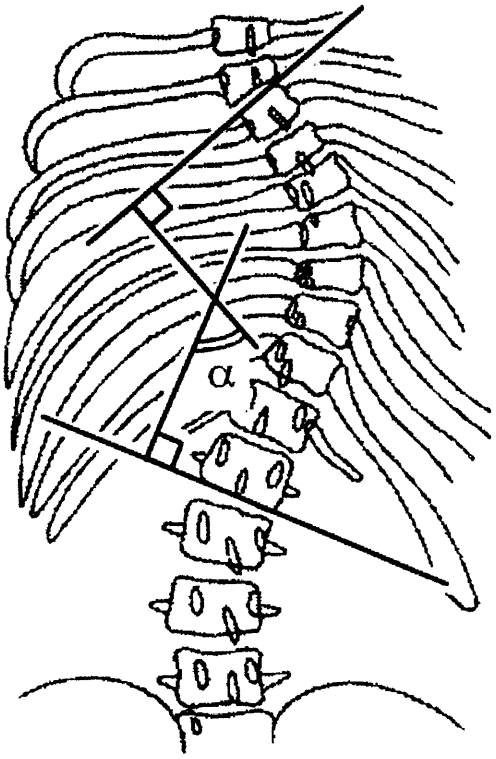


Figure 2-6
Scoliosis is characterized by lateral deviations in the spine.

2.3 Spinal Fusion

Spinal fusion is defined as a procedure that involves fusing together of two or more vertebrae in the spine using either bone grafts or metal rods [29]. The goal of any surgical fusion of joints is to alleviate pain, correct deformity, and restore stability. For spinal fusion there are two goals; to achieve solid fusion and to eliminate the patients pain.

Decompression and fusion of the affected vertebral level(s) are used to achieve the restoration of spinal stability. Successful fusion rates have been reported to vary from 40% to 98% depending on several factors. Fusion rates are highest for single level fusion and the rates decrease as the number of levels increase. The surgical approach used to access the spine can affect the rate of fusion, as well. Typically, anterior approaches to the spine yield better fusion results than posterior approaches, because the spinal musculature and nerves are not disturbed during an anterior spinal surgery.

The use of internal fixation devices dramatically increases the rate of fusion, offering enhanced stability to the spine while fusion is taking place. Fusion rates typically increase when bone graft harvesting is taken from the femur of the patient, which is referred to as autogenous bone graft. However, there are other possible harvest sites and techniques for bone grafting that will be addressed later. Underlying conditions and various patient habits such as smoking, contribute to the outcome of the surgery as well.

Many factors influence the outcome of spinal fusion surgery with respect to pain relief. The following is a list that should be considered when evaluating treatment failures:

1. Diagnosis

   - most commonly, failure to identify additional levels of involvement

2. Technical Failure

- likelihood of failure increases as number of levels increase
- pseudarthrosis (lack of bone fusion), is not always painful, but persistent pain should be considered pseudarthrosis until proven otherwise.
- late failures (> 1 year) are often a result of degenerative changes at adjacent levels.

3. Other

- divergence of patient and surgeon expectations
- issues concerning compensation and insurance benefits
- psychological factors including depression, hypochondria, hysteria, substance abuse.

Recent reports on the results of spinal fusion have reported success rates in the range of 80 to 90% for pain improvement and 50 to 75% for return to work.[9] Pseudoarthrosis rates are about 5 to 10% for one or two level fusions. Infection rates range from 2 to 5%, and nerve root injuries occur in about 1% of cases where pedicle screw fixation is used [23]. Perhaps the less than 100% success rate is due to patient selection.

2.3.1 Operative Techniques

Operative techniques have evolved as the indications have broadened. Posterior, posterolateral, posterior interbody, anterior interbody, and circumferential approaches have been used to access the spine for fusion. Posterior techniques are usually reserved to expose higher levels. However, when obesity, prior abdominal surgeries, and other spinal deformities may make anterior techniques potentially dangerous, posterior techniques will be used to fuse lower levels, as well.

The posterior technique has been supplanted by the posterolateral method, since studies have shown lower rates of non-fusion for posterolateral surgeries. Posterolateral intertransverse process fusion is the most common type of fusion performed in the lumbar spine for a single-level fusion. Posterolateral fusion has been the standard technique for many years. Studies have reported a pseudoarthrosis (non-fusion) rate of about 5% for L5-S1 fusion and in the range of 10% to 20% for L4 to L5 fusion[3]. Posterior lumbar interbody fusion has not gained wide acceptance because of the technical difficulty of the procedure.

Renewed interest in anterior fusion offers several potential advantages over posterior and posterolateral techniques. Advantages of anterior approach include stabilization of the anterior halves of the vertebral bodies, posterior (middle) halves of the vertebral bodies, and posterior halves of the vertebral bodies columns of the spine, whereas, posterolateral arthrodesis stabilizes only the posterior column[3]. Anterior spinal fusion avoids disruption of the intrinsic muscles of the lumbar spine.

Typically, anterior approaches are used to expose lower vertebral levels, from L5-S1 to L4-L5 and sometimes even as high as L3-L4. Compression loading during anterior surgeries provides a more favorable mechanical environment for fusion. A more rigid

segment is treated, with a (theoretically) higher certainty of alleviating pain. Internal fixation devices have also been developed and tested to facilitate anterior fusion. Anterior interbody fusion may directly address the problem of intervertebral disc degeneration and related pain[22].

Circumferential Fusion (combined anterior and posterior fusion), has received less scrutiny because there are fewer indications for it, and should be reserved for cases where instability due to severe spinal deformity is an over-riding issue. Theoretically, a higher rate of fusion is achievable. Circumferential fusion is very useful for long fusion to the pelvis. However, this technique is extremely traumatic for the patient, since two operative incisions are used[22].

2.3.2 Fusion Cages

Fusion cages are used to provide fixation and promote bone growth between the affected vertebral levels. The rate of bone growth between vertebrae is very slow and without these fixation devices fusion would be impossible. The two major categories of fixation devices used today are the traditional pedicle screw and the new interbody fusion cage.

Pedicle Screw Instrumentation

The mechanical reality of spinal fusion is that bone graft alone is not enough to fully support the load seen by the lumbar spine. If fusion does not take place quickly, the

pedicle screw device will have to absorb all of the load distributed down the spine. One compelling reason for this is that the disc continues to be loaded after solid posterior fusion has taken place. Internal fixation devices, such as pedicle screw instrumentation, were incorporated to improve on fusion rates. However, these systems do not unload the disc and their use can generate new and occasionally serious complications[39].

A diagram depicting how a pedicle screw fixation device is used to stabilize two vertebral levels is shown in figure 2.3.1. Mechanical analysis of a loaded spine, under normal conditions, shows that 75-100% of the compressive load passes through the intervertebral disc.

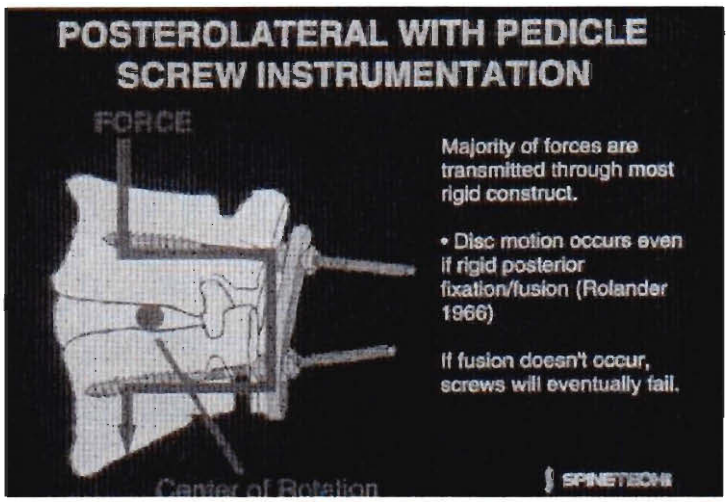


Figure 2-3-1
Pedicle screw fixation

As seen in figure 2.3.2, the load is distributed through the fixation device, which eventually causes the screws to fail if fusion doesn't take place quickly.

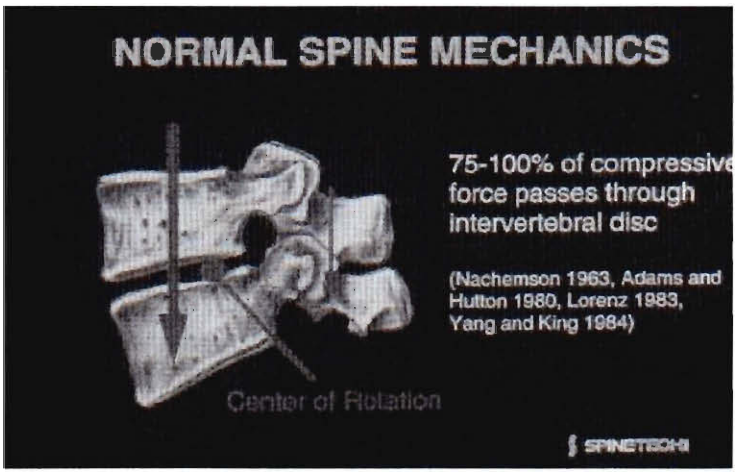


Figure 2-3-2
Intervertebral Load Distribution

Failure of pedicle screws is attributed to the somewhat high rates of non-fusion, and long lasting patient discomfort[9, 39]. Pedicle screw instrumentation has been the "gold standard" to improve alignment, stability and fusion rates for many years, but less than perfect and unpredictable results have led to the development of new techniques in vertebral fixation.

Interbody Fixation Devices

Until recently, fixation devices were comprised of screws or bolts, which were used to secure cables, rods, or plates to the spine. These have all shared the disadvantages of requiring large exposure for device insertion and somewhat bulky construction, risking vascular injury, along with the already mentioned failure rate of many devices. Interbody fusion cages have been developed eliminating many of the imperfections of the pedicle screws[12].

Interbody cages, can be square or cylindrical tubes, which fit directly in the vertebral space securing both the upper and lower vertebral spaces. The BAK interbody fusion cage, produced by Spine -Tech Inc., was the first interbody fixation device developed and is shown in figure 2.3.3. These, hollow, porous titanium devices are square threaded and slightly tapered. The surgical procedure involves implanting two threaded cylinders into the disc space at the affected vertebral level to restore normal disc height, provide three-dimensional stability to the affected area, and minimize microscopic motion.

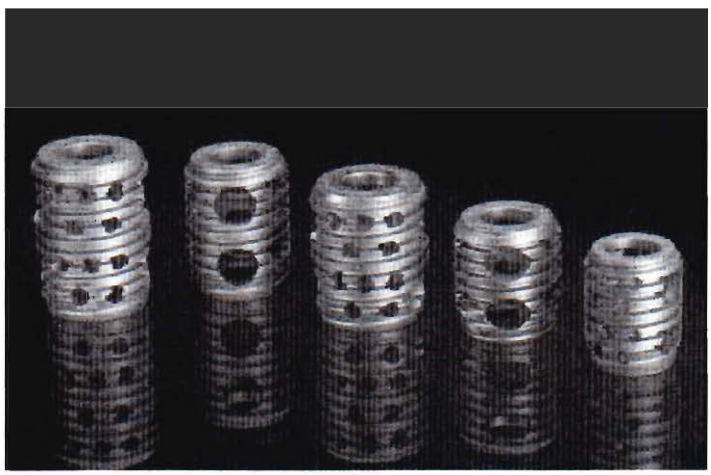


Figure 2-3-3
BAK Interbody Fusion cages

The BAK fits directly into the disc space, therefore not changing the natural weight distribution of the loaded spine. When filled with morselized bone graft, it provides stability and the biological ingredients necessary for fusion to occur and will eliminate the need for precisely fit bone grafts. The device is strong enough to withstand spinal forces without deformation or fracture, yet porous enough to allow through-growth of cancellous bone. Perhaps most importantly, the procedure required to implant these devices is significantly less invasive than the pedicle screw instrumentation.

BAK success rates are reported as high as 91%, using the open technique[12]. It should be noted that this device set the stage for laparoscopic spinal procedures. To perform a fusion using this cage, instruments have been developed that allow decompression of the disc space, centering of the implant, and placement of two threaded titanium cylinders. Using MRI scans, measurements are taken to determine the size for the intervertebral fusion cages to be used. In most cases, the implants occupy most of the interbody space, and no additional graft is necessary or possible. External braces may be worn for comfort, but they are not required. Walking with or without assistance is encouraged as soon as possible after the procedures. With the exception of heavy laborers, most patients are able to return to employment when soft tissue is healed, usually four to six weeks. A significant increase compared to the result's obtained with pedicle instrumentation[12].

The BAK is FDA approved when used to treat degenerative disc disease at one or two levels of the spine. BAK use is not considered safe for fusion of multiple levels. The success of the BAK predominantly holds for fusion of the L5-S1 and L4-L5 levels and is only used in rare circumstances to treat fusion at L3-L4. As with any spinal fusion, the BAK is recommended for patients between the ages of 21 and 65 years. Who have chronic disabling low back pain of at least six months duration, and are unresponsive to an adequate trial of conservative treatment[39]. Precautions should be taken when any of the following are present: symptomatic vascular disease, malignancy, gross obesity, greater than grade one spondylolisthesis, pregnancy, and osteopenia.

In addition to the cylindrical BAK, a square interbody cage has been developed, called the Proximity. The biomechanics of the square Proximity fusion cages support a larger area of vertebral disc space and offers better stability, than the BAK. However, the

Proximity's present internal structure does not allow for as much bone graft to be implanted, as the BAK. Long term studies are in the process of comparing the BAK and the Proximity cages.

Open spinal surgeries can be performed using BAK interbody fusion devices. This can be advantageous in fusion beyond L3, or in instances where laparoscopic techniques would be difficult. These procedures yield higher fusion rates and damage less tissue than pedicle screw procedures, however recovery time is not as fast as laparoscopic methods.

2.4 Minimal Invasive Procedures

2.4.1 A Short History of Minimal Invasive Surgery

The development and progession of MIS has particularly been a consequence of technological advances. Endoscopy was first described by Hippocrates (c400BC). There was little progress until the 18th century when Arnaud, a French gynelcologist used a small lantern to visualize the cervix, the next major breakthrough was in 1879 with the development of the cystoscope with a series of lenses. The first Laparoscopy was performed by George Kelling in 1901 when he introduce a cysotscope into the peritoneal cavity of a dog, after injecting air to create pneumoperitoneum[39].

In the later part of this century there were three major technological advances which paved the way to modern MIS. In 1954 Professor Harold Hopkins , along with Karl Stortz in Germany, developed a scope which could deliver a bright light at its tip and provide a clear picture with true color rendition. The next major advance was the development of fibre- optic light transmission and by 1963 Herschowitz, working in Ann

Arbor Michigan, produced a flexible endoscope which had one light bundle for visualization and a second for the transmission of light. This was particularly important as it produced "cold light" transmission and obviated the need for a hot light source at the end of the scope. In 1985, the next major break through came with the development of the computer Chip Video Camera, by Circon Dledctronics. With the operation displayed on a monitor, the whole procedure could be seen by everyone in the room. This allowed for more effective assistance and improved visualization. In 1987, the first gallbladder was removed laparoscopiclly. Currently the endoscopic approach is used by virtually all surgical disciplines. The endoscopic approach to the spine is a relatively new addition to the field of Minimal Access Surgery, but the initial experience suggests a permanent place in the history of spinal surgery[39].

2.4.2 Laparoscopic Spinal Fusion

Laparoscopic surgery uses four to five small incisions, approximately 1cm each, instead of one large incision to access the affected area. The larparoscope (a thin telescope like tube) is then inserted through one incision, which displays a magnified image on a TV screen in the operating room. Using the laparoscope as a guide, the surgeon uses the other incisions to insert special tools to work on the affected the area.

Since its introduction in 1987, laparoscopic gallbladder removal (cholecystectomy) has become the procedure of choice when treating gallbladder disease. Once a debilitating procedure, cholecystectomy is now performed on an outpatient basis. Laparoscopic techniques are also widely used by general, urologic, gynecologic, and thoracic surgeons, as well. The advantages are clear: decreased surgical time, smaller incisions, less physical trauma and stress, decreased pain after surgery, less incisional

complications, and more rapid return to daily function. This has led to a decrease in postoperative pain and length of hospital stay, more rapid return to work, and a decrease in the overall costs associated with many procedures. Naturally, these results have encouraged surgeons to apply these techniques to other areas of surgery, as well. The first accounts of laparoscopic techniques being applied to spinal surgery were in 1991, when a lumbar disc was removed laparoscopiclly. Since then, the positive results of laparoscopic spinal fusion have led many orthopedic surgeons to adopt the technique.

Two different approaches have been used to perform this procedure: retroperitoneal and transperitoneal techniques. These techniques differ by the location of incision sites and patient positioning on the operating table, thus changing the surgical approach to the spine. Thus far, surgeons have had success with both techniques. The transperitoneal technique offers some technical advantages such as better visualization of surgical anatomy, decreasing some operative complications, and patient factors such as lessening of postoperative pain. Retroperitoneal lumbar fusion reduces the risk of retrograde ejaculation, because the autonomic plexus is not dissected, in contrast to transperitoneal laparoscopic approaches. Also, with the transperitoneal approach, if the surgeon reams, taps, or drills too deeply, the spinal canal is at risk. With the retroperitoneal approach, however, the orthopedic drilling, reaming, and cage insertion are directed toward the psoas mucle instead of the neurologic structures. A major draw back to the retroperitoneal approach is that in some patients, a fusion at the L4-L5 level may require the removal of a part of the iliac crest[12]. Overall, we have observed many more laparoscopic transperitoneal spinal fusions, suggesting that more surgeons favor this approach, for some of the technical reasons stated above. The decision is largely up to the doctor and depends on what he or she feels is the most appropriate for the given case.

2.4.3 Indications

As with open spinal fusion, the underlying symptom to treat with laparoscopic fusion is mechanical back pain. The current surgical indications for the use of laparoscopic spinal fusion are degenerative disc disease, internal disc disruption, and pseudarthrosis. Greater than grade one spondylolisthesis and segmental instability patients have not been considered candidates for laparoscopic fusion, as of yet. The ideal patient for the laparoscopic fusion procedure is one who has degenerative disc disease, with signs of disc space narrowing, end-plate sclerosis, and osteophyte formation[43]. Patients with multiple level degenerative disc disease, osteoporosis, or are older than 65 are not good candidates for this procedure, since the surgery requires good end-plate strength.

Laparoscopic spinal surgery has not only been shown to be a safe and effective procedure, but a much more patient friendly procedure as well. Comparative studies have shown that the average hospital stay was 5 days following open spinal surgery with pedicle screw instrumentation, and 1.8 days for laparoscopic patients using the BAK interbody cage[9]. In open procedures, extensive layers of muscle are stripped from the bone and internal organs are manipulated more forcefully than in the laparoscopic procedure.

Two-year follow-ups have shown radiographic fusion in 80% of open procedures (with pedicle screw instrumentation) and 100% in laparoscopic procedures (with BAK interbody cages), and 73% and 100% satisfaction rates, respectively. These discrepancies in fusion and satisfaction rates bring up an interesting point, that successful decompression and fusion do not always relieve patients of their back pain.

Sixty-seven percent of patients operated on using open techniques and pedicle screw instrumentation for single level degenerative disc disease returned to work in an average of 21.4 weeks after surgery. Eighty-five percent of patients with laparoscopic BAK fusion returned to work in an average of 11weeks. It is worth noting that these results plot open pedicle screw fixation vs. laparoscopic BAK interbody fusion. Open procedures cause significantly more tissue damage than laparoscopic procedures, increasing recovery time and post surgery discomfort. Also, as mentioned earlier, pedicle screw instrumentation has been shown to be less effective than the BAK interbody cage in promoting arthrodesis. This study compared the "gold standard" of present spinal fusion surgery with two of the more technologically advanced techniques. None the less, similar success rates have been achieved using the laparoscopic approach[9,12, 30, 36, 39].

2.4.4 Laparoscopic Procedure

The first step in performing a laparoscopic spinal fusion using a BAK interbody fusion device is the bone graft harvest. Although, the size of the bone graft required for BAK cages is less than when pedicle screw instrumentation is used, the harvest site is still a source of post-operative patient discomfort. Next, the peritoneal cavity is insufflated using carbon dioxide and the laparoscopic surgeon exposes the disc space. Exposure of the disc space requires the skills of an experienced laparoscopic surgeon, thus the procedure is usually performed by both a laparoscopic specialist and an orthopedic surgeon. Once the discs are exposed, the great vessel is usually mobilized depending on what vertebral level is being exposed. In most patients, the L5-S1 disc

level can be exposed below the great vessel, as seen in figure 2.4.1. As shown, the exposure of L4-L5 (and above) requires that the left iliac vein or vena cava, be pulled off to the side.

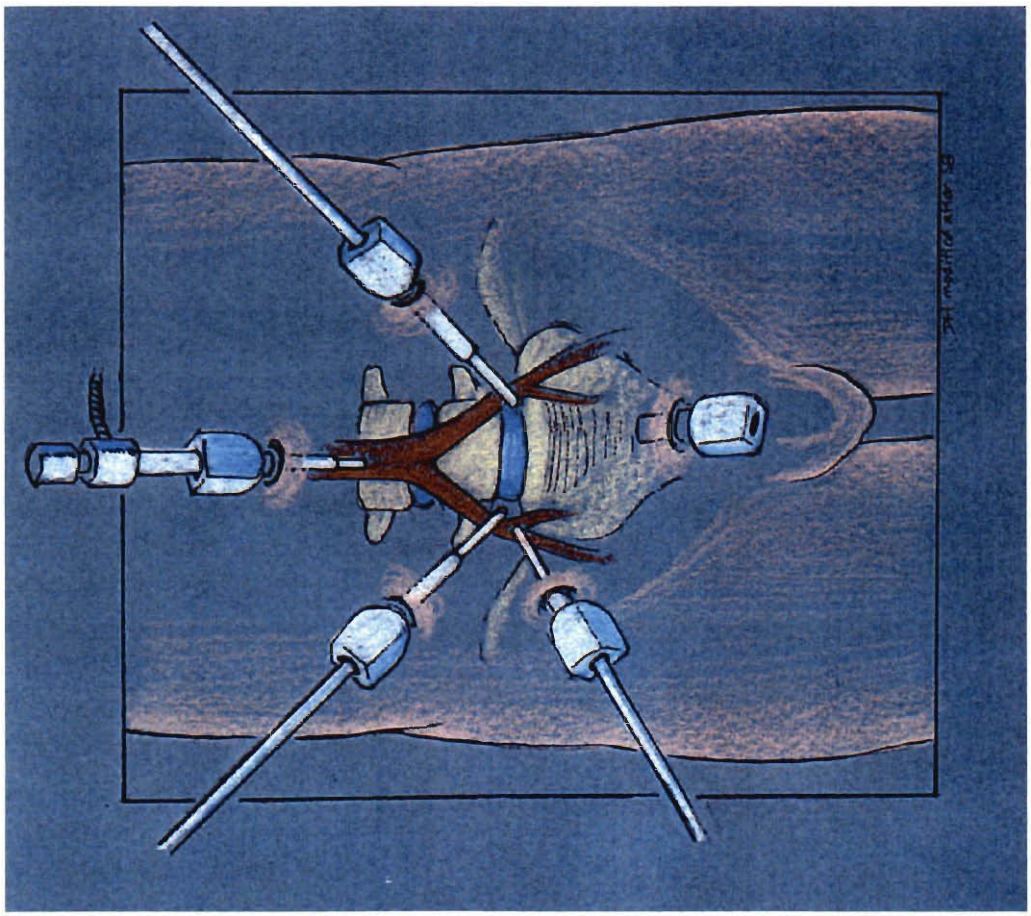


Figure 2-4-1
Laparoscopic instruments working below great vessel to perform fusion at L5-S1

Great care is taken to mobilize these vessels since a laceration would be serious and could warrant an immediate conversion to an open procedure if the bleeding can not be controlled. Although, great vessel injuries can and do occur, it is usually in the

laparoscopic surgeon's early experience with this procedure. As with all laparoscopic procedures there is a steep learning curve associated with spinal fusion, also.

The orthopedic surgeon marks the disk space midpoint and the initial holes are drilled between the vertebral levels that are to be fused. A series of distraction plugs are impacted into the compressed disc space, until the desired vertebral height is achieved. BAK cages, filled with morselized bone graft, are then inserted into the decompressed disc space. The implants are aligned parallel to one another and should be contained within the interbody space. Additional bone graft may be inserted between and around the implants if desired. In most cases, however, the implants occupy most of the interbody space and no additional graft is usually necessary, or possible[39].
Once both cages are in place, the operated space is inspected and the area is closed.

2.4.5 Complications

Overall, using laparoscopic interbody fusion techniques for the already mentioned indication's, has been established as a safe procedure.

- No vessel or organ injuries
- 1 mal-postitioned cage
- all patients had ileus > 2 days

Hospital Stay and Learning Curve

- all same day admits
- average 5 days
- average OR time 3 hours

Contraindications for Laparoscopic BAK Implantation

- Peritoneal or pelvic infection
- Previous open anterior surgery of the lumbar spine
- Gross obesity
- Previous lower abdominal surgeries
- Previous Laparotomy

Following the guidelines above, laparoscopic spinal fusion for a transperitoneal approach to L5-S1 has been established, as a safe procedure. Laparoscopic transperitoneal L3-L4 & L4-L5 exposure can be achieved safely to facilitate minimally invasive lumbar spinal fusion, however, complication rates increase with upper level exposures.

2.5 Muscle Sparing Approach

The treatment of degenerative disc disease requires a surgical procedure that obtains both stability and neural decompression, involving foraminotomy (widening of intervertebral spaces to allow free passage of the spinal nerves) and lumbar fusion, performed either anteriorly or posteriorly. The rate of successful fusion is improved by the placement of rigid instrumentation such as rods or plates with screws that prevents motion during the process of fusion. Previous open anterior approaches have been hampered by the approach necessary to access the disc space and the lack of instrumentation tailored to the approach. The *muscle sparing approach* is a modified version of traditional open surgery, using much of the same equipment, but makes a smaller incision through the abdominal muscle. This procedure claims to offer patients shorter hospital stays and quicker recoveries, than the traditional open surgery. This procedure is associated with a low complication rate, pain relief of 90% at 2 years, and a fusion rate of 70% to 95% at 2 years. However, along with these results come significant muscle splitting incisions, 4-6 day hospital stay, and a loss of employment for 3 to 6 months after the procedure. Also, even with fusion young patients may continue to experience back fatigue and weakness secondary to muscle loss.

Using transperitoneal approach, once the L5-S1 disc space is properly exposed the surgeon places a pin into the 20-mm port to ensure colinear placement of the laparoscopic hand dill. Using this drill the surgeon inserts a distaction plug into one site of the disc space and left the plug in place to levitate the disc space. Then creates a satisfactory hole for the implant. The surgeon uses a bone graft from the patient's iliac crest and places the graft into the implant. The distraction plug is then removed from the opposite side and repeated the implantation procedure for the other side. Cancellous bone grafts were

added to each implant using a laparoscopic bone impactor through a 20-mm port. The bone is placed to begin the process of actual fusion, which takes approximately six months. Once the implants were properly placed the procedure was complete.

Some doctors feel that the muscle sparing technique offers the best of both worlds. Decreased surgical time, decreased tissue trauma, faster recovery/rehabilitation, along with direct visualization of the spine[8]. However, laparoscopic lumbar procedures do not offer direct viewing of the Spine. The muscle-sparing paramedian retroperitoneal approach using a small transverse skin incision (6-10cm), it is possible to view the spine directly. With little morbidity to the patient, safe mobilization of vascular structures, choice of variable anterior strut devices, and ability to achieve proper sagittal alignment[25].

The open MIS approach requires a transverse skin incision midway between the umbilicus and the pubis along the patient's natural skin creases on the left side of the abdomen. Average length of stay was 7.4 days (range, 5-10). The average duration of surgery for the anterior spinal fusion was 1hr 57 min (range 1-5.5hr) and that for the posterior spinal fusion was 3 hours 52 min. AV EBL was 244cc (range 50-750cc) for both procedures done on the same day 816cc. The posterior instrumentation and fusion was the most involved portion of these cases. There were no complications with this procedure[25].

The muscle sparing retroperitoneal approach allows direct visualization and access to the lumbar spine while preserving the abdominal oblique musculature. In addition to the advantages of an open procedure (improved exposure and arthrodesis technique), sparing the muscular incision allows quick postoperative recovery. As seen with the laparoscopic technique, patients undergoing this procedure have had no

complaints with abdominal pain. Length of incision is usually 8cm depending on the size of the patient, compared to four o five 1-2cm portal incisions. Although the length of stay is longer as compared to reports from most laparoscopic procedures (3.6 vs. 7.4 days), all of these procedures were anterior/posterior where most lap reports are just for anterior alone. Laparoscopically assisted anterior lumbar fusions are commonly performed on patients with painful disc degeneration or simply a disc herniation. These patients are undergoing single level intervertebral procedure without needing posterior instrumentation or a decompressive procedure. The muscle sparing technique provides good exposure of the lumbar spine, allowing for a traditional fusion techniques using familiar spinal instrumentation and choice of strut device. For surgeons not comfortable with laparoscopic techniques, or in instances where the laparoscopic approach is not possible, this procedure offers patients an improvement to the old standard.

2.6 Bone Grafts

Currently, spinal fusion usually involves harvest of bone autograft from the pelvis. Anterior fusion was performed originally with autogenic graphs usually harvested from the iliac crest. However, the incidence of complication at the donor site is high. Complications such as chronic pain, nerve and arterial injury, peritoneal perforation, sacroiliac joint instability, herniation of abdominal contents through defects in the ilium, dysesthesia, hyperestheisia, bleeding and infection have been reported, with an incidence of approximately 30 percent [28]. Intraoperative complications were bleeding from a segmental vein, and damage of the lateral femoral cutaneous nerve. Consequently, spine surgeons began using allogenic grafts to avoid these complications.

Most surgeons accept that fresh autogenic bone provides the best available graft material, although surgical harvesting of autogenic bone from the iliac crest is not without complications. Complications are superficial or deep infections, seromas, hematomas, vascular injuries, neurologic injuries and iliac wing fractures. Even in the hands of experienced spine surgeons, donor site pain may be present in as many as one third of patients. To minimize the possibility of iliac crest fracture after bone graft harvest, bone should be removed at least 30 mm from the anterior superior iliac crest. An ideal graft should be osteogenic, osteoinductive, and osteoconductive [3]. However, when anterior fusion routinely is combined with posterior fusion, the stability is high, so allogenic grafts may be sufficient.

Autotgenous iliac crest bone graft is currently the gold standard graft material for posterolateral lumbar intertransverse fusion. Even with the widespread implementation of internal fixation devices, nonunion instances remain problematic. This has lead to a

search for bone graft alternatives that hold the promise of eliminating both donor-site morbidity and nonunion of the fusion site[3].

Bone graft alternatives can be classified into three functional categories.

1. Graft extenders, when added to autogenous bone, allow for the arthrodesis of a greater number of levels, or the use of less autogeous bone, and yield a rate of successful fusion equal to that of autogeous bone graft alone[13].
2. Graft enhancers, when added to the usual or a decreased amount of autogenous bone, yield a higher rate of successful fusion than auotogenous bone graft alone[13].
3. Graft substitutes, which completely replace autogenous bone, yield a comparable or increased rate of successful fusion compared with autograft. Results indicate that there was no significant difference in the fusion rate in autogenic bone grafting compared with allogenic bone grafting[13].

Bone allografts are used commonly in spinal surgery. In the lumbar spine, allografts had a limited role in posterolateral fusion. For anterior body fusion, structural allografts have been successful. A legitimate criticism of anterior structural allografts is that it is necessary to use fresh frozen bone to preserve the structural integrity of the graft.

When using fresh frozen bone, there is the potential of virus transmission. In the current study, donors with Human Immunodeficiency Virus (HIV), and hepatitis were excluded to minimize the risk of infection.

Numerous operations have been proposed for treatment of symptomatic spondylolisthesis after failed response to conservative treatment. Anterior lumbar interbody fusion combined with some type of posterior fixation is one of the standard treatments for symptomatic spondylisthesis. However, pseudarthrosis is one of the complications associated with the method of this treatment. Combined anterior and

posterior lumbar fusion using autogenic bone grafts results in a far lower pseudarthrosis rate than in anterior body fusion [3].

The use of banked femoral headbone is a safe, simple, and most inexpensive method or harvesting bone. Total operative time and blood loss can be reduced, and possible complications associated with the donor site can be avoided. Adequate preoperative planning and proper surgical technique will always reduce the incidence of any complications.

2.6.1 New Developments in Graft Technology

Bone Morphogenetic proteins (BMPs) are a group of related proteins originally identified by their presence in bone-inductive extracts of demineralized bone. Recently, they have been synthesized via recombinant techniques using Chinese hamster ovarian cells. At least six related members of the BMP family have been identified via molecular cloning (BMP-2 to BMP-7) [13].

The BMPs are part of the transforming growth factor beta (TGF-β) superfamily[6]. They have the biologic capacity to induce the differentiation of perivascular mesenchymaltype cells into cartilage, which then is replaced by bone through a process of enchondrol ossification. In general orthopedics, BMP has clinical potential as a bone graft substitute and for use in spinal surgery. A recent study (by Boden et al) showed that an eightfold increase in the bone-derived osteoinductive growth factor concentration that was needed to induce adequate bone formation in the rhesus monkey spine (posterolateral lumbar intertransverse spine fusion) [6].

This study investigated the efficacy of Recombinant Human Bone Morphogenetic Protein 2 (rhBMP-2) with an absorbable collagen sponge carrier and a dowel allograft in

promoting spinal fusion in the rhesus macaque monkey using an anterior interbody fusion model. An allograft, and sponge were stored in a petri dish of 1.5mg/mL for 1 hour. These contents were then placed in BMP-2-soaked allograft cylinders, which were implanted.[21] The monkey's receiving rhBMP-2 soaked collagen sponges with freeze dried allograft demonstrated radiographic signs of fusion as early as 8 weeks. The control monkey's (without the BMP) were slower to reveal new bone formation [6].

In this study, the authors were able to document the efficacy of rhBMP-2 and cortical dowel allograft with an absorbable collagen sponge carrier and a cortical dowel allograft to promote anterior interbody fusion in a nonhuman primate model. The rate of new bone formation and eventual fusion with the use of rh-BMP-2 and cortical dowel allograft appears far superior to that of autogenous cancellous iliac crest graft, with cortical dowel allograft.

The posterolateral spine is a particular challenging healing enviroment for bone formation, due to the low blood supply received by intervertebral bodies. BMP has been used successfully in rabbits, rhesus monkey's, goats, and sheep. These proteins may find there way into use in humans, however, if their efficacy is less than 100% they may never be used due to high manufacturing costs[13].

2.7 Patient Care

While decompression and spinal fusion is the most effective procedure to relieve patients of persistent back pain, the relief of all back pain is rarely 100%. Thus, patients have to assume responsibility for their own care, which includes maintaining the postoperative activity level (i.e. walking as much as possible) designated by the surgeon and/or physical therapist.

Before spinal surgery, a nurse assesses the patient's understanding of what is expected of him or her as an active participant during the recovery period. The nurse also provides information about the risks associated with spinal surgery. Possible complications associated with laparoscopic procedures are: bowel or organ damage, mechanical complications resulting from use of trocars, oxygen retention in the abdomen, chest, blood stream, and around the lungs; decreased oxygen to local tissues, infection in the abdominal cavity, carbon dioxide absorption, formation of cysts in the lymph nodes, and herniated incision.

A nurse also administers pre-operative information regarding the day of surgery.

- Expected arrival times at the hospital on the day of surgery,
- The importance of being NPO* before surgery,
- The approximate length of stay, events on the day of surgery (i.e. preoperative holding experience),
- Entry into surgical suite, post-anesthesia care unit (PACU) stay, inpatient unit care,
- Their planned food and water intake progression after surgery (i.e. IV fluids and progressing to liquids, then solid foods),

** NPO: Latin abbreviation for nothing by mouth*

- Postoperative physical therapy, and postoperative pain management.

After any spinal fusion, walking with or without assistance is encouraged as soon as possible after the procedures. For open spinal fusion patients, activity out of bed is not started until 3 to 5 days after the procedure. With laparoscopic patients' the physical therapist assists the patient in walking on the first postoperative day. Furthermore, no postoperative bracing is required, unlike traditional open spinal surgery. In both cases, the patient can walk as much as he or she can tolerate. Promoting mobility is a key ingredient to the recovery process.

Patient stays after laparoscopic fusion has been dramatically shortened from the previous open techniques. An open spinal fusion entails a hospital stay of at least one-week, whereas patients undergoing the laparoscopic fusion procedures with implants stay only two to four days,[32] and in some cases less. A recent study boasts an average hospital stay of 1.7 days, ranging from 0 to 2 days, where 9 of the past 18 cases were done on an outpatient basis[36].

Patients pain levels throughout the post-operative course are less than with a comparable open procedure. In open spinal fusions, layers of muscle are stripped from the bone and pulled open, and internal organs are manipulated more forcefully, than in the laparoscopic procedure. The patient receives IV narcotics for one to two days after surgery and then is given oral analgesic medication as soon as food is tolerated. Preoperative and postoperative antibiotics are administered, as well.

After the patient is capable of eating solid food and can move about with the use of an assistive device (i.e., walker, cane) or alone, he or she is ready to go home. Patients are advised not to carry anything heavier than 5 pounds until their return visit to the

clinic/doctors office. Driving is restricted until permitted by the surgeon. Patients are also advised to avoid twisting motions of the trunk.

The activity level that is required during a patients normal work- day (i.e., sedentary, light to moderate, heavy) plays a determining factor on the return to work status, and varies on a case by case basis. Thus, there is a great deal of fluctuation in these numbers. Patients who have had open spinal surgery with instrumentation return to work on an average 21 weeks, where patients with laparoscopic surgery return on an average of 11 weeks.

The first return visit is usually within seven days following the procedure. During the first postoperative visit, a nurse will assess the patient's wound and remove skin sutures if appropriate. When sutures are removed no bandages are required. The patient is encouraged to walk as much as he or she can tolerate to promote recovery. The nurse then answers any questions that the patient might have such as: pain medications, proper diet, activities, and status of the implants. The surgeon usually answers any medical concerns that the patient may have such as: "How will this procedure affect any current medical conditions I have?" "Will my recovery be different than that of any other patient's?", and any other questions the patient may have. The patient begins physical therapy a few weeks after the procedure to strengthen spinal muscles and increase endurance. The follow-up office visits also include physical examinations performed by the surgeon and review of the patients x-rays with the implant depth and progression of fusion noted.

Chapter 3: Understanding Consumer Innovation Adoption

In the next portion of this outline, we will attempt to make clear, how the understanding of consumer inertia in innovation will be essential for the success of our brochure. We felt that an understanding of how consumers relate to adopting an innovation would give us some insight for the design, and the contents of our brochure.

Innovation and its Implications

Innovations can be classified as an invention, something that is completely different from anything already in existence. However, an innovation might not be a material product, but more of an improvement of a well-established procedure, or a fundamental change[1, 2,4,5,10]. Some fundamentals we will discuss are how consumer inertia can affect a new innovation, or in our case, a new surgical procedure. These fundamentals are:

- Cost
- Complexity
- Visibility
- Compatibility

Cost

Any new product that is first introduced to the market that has high financial properties will likely be accepted more slowly than those that do not. Even if the outcome will increase the probability of higher acceptance. People in general will accept a lesser quality product knowing that the price will be appropriately lower. While the risk associated with adopting an innovation may not only have cost factors considered, but more of ones that do not have financial implications. For example: a new approach to a medical procedure may require some experienced general practitioners to forsake

traditional approaches in favor of new clinical practices, resulting in temporary lower competence levels. The level of insecurity from inexperience may be thought as not worth the risk, and the possibilities of acceptance will be diminished. The high price, which might have to be paid, is the personal factor that each individual undertakes [4,17,19,37]

Complexity

There are many examples of how complex some innovations are, that apply to a level that even the smallest of children can understand. For example, common household appliances were invented because of a need to eliminate problems occurring every day that consist of complex components, circuitry, and hardware, as well as software. These appliances exist in households throughout the world. [18,27,34,40] Ideas and practices that are relatively simple to understand are generally adopted more readily and quicker, than those with greater complexity.

Visibility

An innovation is likely to be adopted more quickly and more widely if it is open for inspection, and if it can be seen to work. Knowledge must not only be transmitted but also received if it is to have any chance of being acted upon. It is essential that in addition to being received, it must also be understood. This is why an effective mean of communication must be implemented for quicker adoption [18,27,34,40].

Compatibility

The attitudes and values which most people hold in relation to an innovation tend to be affected by their past experiences with related ideas. The innovation must not conflict with the values and beliefs that already have been established, otherwise the innovation has little chance of success.[34,27] If something new can be seen to be a major

improvement on what currently exists then it could well be adopted fairly quickly. A rational decision is made on the basis of assessing the probable advantage of making changes. Some thought has to be considered of what improvement, if any will be made.[27,34,40]

Our thoughts are, to produce a brochure that will cover techniques, and procedures that have been considered new. In attempting to provide the reader of the brochure with new and innovative developments, considerations for consumers in accepting new ideas and innovations have to be met. In understanding this, we can now move forward in our data collection by implementing these concepts of understanding, and setting a goal for our brochure to make them clear.

Chapter 4: Methodology

In our attempt to gather information for an informative brochure, we decided it would be important to gain further insight into the experiences that patients have faced with spinal fusion surgery. We felt that in order to relieve patients' fear and anxiety, qualitative data was required. We searched, and considered various methods to acquire qualitative data, and which method would be best in our case to use. We consulted our project advisors on this matter, and decided a detailed questionnaire would be the most effective method to obtain such data.

4.1 Human Relations

By interviewing doctors, nurses, and asking them what was at stake, we were able to develop an inventory of what we thought would matter to the patient having surgery. In conjunction with UMMH orthopedic and neuro-surgery center, and our project advisors, we formulated a questionnaire that was administered to patients (post-operatively). All personnel involved agreed that this would be an integral part of an informative brochure.

In embarking on this task, we encountered some difficulties in obtaining access to patient data. We contacted specialists, neurosurgeons, general surgeons, orthopedic surgeons, hospital administration, and staff at UMMH. We found that it was almost impossible to contact patients because of legal issues concerning patient confidentiality. In order to overcome, and follow through with our questionnaire, we were required to submit an application to the Human Relations Committee (HRC) of UMMH. We were fortunate enough to work with some very helpful individuals that helped expedite the process of acceptance.

Within three weeks of submission to the HRC, signatures of principal investigating surgeons, departmental approval, and administrative assistance, we gained approval. The questionnaires were initially to be distributed to patients on their first follow up clinic visit, two weeks after surgery, with the stipulation of only one questionnaire per patient. Small info-meetings were set up to inform the nurses at the clinic of the procedure for administration. A sample application of the questionnaire to the HRC of UMMH is provided in the appendix.

4.2 Formulating Effective Questions

The objective for our questionnaire was clear; to obtain personal accounts describing each patients experience with spinal fusion surgery in a short, concise questionnaire.

Overall, we needed to communicate effectively to those who may not be able to understand medically oriented questions. It was critical that this questionnaire be written for the average person to read and understand. We thought that the questions should be answered with minimal effort, that is, by giving the reader a selection of either yes or no answers, or some specific answer choices in hopes of increasing the rate of response. Next, we had to consider the types of questions to ask that would provide us with the information we needed.

First, we needed to ask questions that would categorize patients based on their medical history and the type of procedure performed, so that we could accurately interpret their responses. Second, we had to formulate questions that would describe the patients experience with their condition. Lastly, questions about the procedure itself,

while avoiding open-ended questions, and without acquiring information that would be considered unusable.

4.3 Categories

We asked four questions in the opening page that were for a nurse or a physician to respond to, regarding diagnosis, technique, surgical approach, and fixation devices. The reason for having a section with nurse or physician responses, was that we felt that these medical questions were perhaps too difficult for the patient to answer accurately. We provided the medical professional with several choices of diagnoses, operative techniques, approach to the spine, and the type of fixation device used to stabilize the spine. The importance of these types of questions was to provide us with placement of respondents into categories.

4.4 Patient Questions

Condition information 4.4.1.

How many months have you had this condition?

We felt it was necessary to investigate the longevity of patient symptoms. We felt that this could place the patient in a category related to the average amount of time that each patient had symptoms. The thought behind this question was fairly obvious, in that we could show direct relationships to the reader of the brochure, knowing how long an average spinal fusion patient has had symptoms.

Was this the first spinal fusion surgery you have had?

We needed to be sure about the symptoms of the surgery, and if it may be related to a pre-existing condition. The patient may have a pre-existing condition that may skew the results of people who had no previous surgery, and in such case, the response would be noted for those specific circumstances.

Was the injury work related?

We wanted to show the reader that in certain instances, work related injuries might be a source, and a cause of back pain symptoms.

Are you a smoker?

If so, how much do you smoke?

Were you ever a smoker?

We felt it important to include a number of questions about smoking habits. Upon consultation with a neurosurgeon at UMMH, he informed us of problems associated with cigarette smoking, and we felt that this would be an important area to address. We anticipated that we would be able to make generalizations about the risks associated with smoking. We thought we could make some recommendations about how the surgery will have a better chance of a successful fusion rate if the patient stops smoking before the surgery. As stated earlier, we have found that people who smoke cigarettes have a higher rate of unsuccessful spinal surgery.

4.4.2 Lifestyle issues

We thought an informative brochure should include questions about the flexibility, level of activity, or if their social life has been reduced because of back pain problems.

How many times did you meet with the doctor (who performed your back surgery) before the operation?

Before your back surgery, how often did your back problems prevent out from doing activities that require strength or flexibility, such as golfing, active sports, heavy housecleaning, gardening, heavy lifting, etc?

Before your back surgery, how often did back pain prevent you from doing light to moderate activities, such as washing dishes, cooking, light cleaning, going up stairs, light lifting, etc.?

Before your back surgery, how often did back pain interfere with your social life, that is, visiting friends, eating out, etc.?

From these questions, we could suggest to the reader some important recommendations about the severity of their symptoms. By knowing the level of pain that a person is suffering, we could make some comparisons before and after the procedure. This would be important for the reader to know if patients had changes in their level of pain.

How would you rate the level of pain you experienced on a typical day before you had back surgery?

How would you rate the level of pain you experience on a typical day now that you have had back surgery?

4.4.3 Comparisons of Pain Before and After

It was imperative to include the pain level before and after the surgery. This question was fairly obvious and straightforward. We thought it was necessary to compare the pain level before and after surgery to show how well a specific procedure worked. Th reader was prompted to respond to a scale of 1 to 6. The least amount of pain was indicated by number 1, and number 6 being the most severe level of pain. Some questions were asked about medications, types of, and the frequency of medication taken. In the case of the specific types of medication taken, the reader was prompted to provide the drug name.

What medications did you take for your back before surgery?

How many times per day, week, or month do you usually take this medication?

What medications do you take now?

How many pills do you take each time?

We felt it necessary to ask about medication so the brochure could provide the reader with some examples of the medication that people use. The recovery of the procedure and ultimately the rate of bone growth are directly related to the lifestyle of the patient.

4.5 Procedural Questions

We wanted to know what helped make the patient make the decision to have surgery, and questions and concerns with the procedure that they had to face.

Did your doctor discuss the possible complications with you?

Did you have any questions or concerns about the surgery?

What helped to answer your questions and relieve your concerns?

Did the doctor provide educational information to you regarding your condition and surgery?

What helped you make your decision to have surgery?

We felt by asking the patient about the procedure, we would be able to provide the reader of the brochure with important answers that the people who had surgery, questioned. This would make it more clear to what instructional information should be known to the patient.

4.6 Satisfaction

We thought that this section would be one of the most important areas to cover. This is how the patient can judge based on their personal feelings how they felt about the outcome of the procedure.

Overall, are you satisfied with the results of the procedure?

We prompted the patient with a yes of no question, and provided a section to where the patient can comment further on whether or not they were satisfied or otherwise.

The remaining questions were regarding payment difficulties, and if the patients' bills were covered under workers compensation.

Did you have any difficulties paying for the procedure?

Are any of your hospital bills being covered by workers compensation?

We thought these questions would be helpful for an assessment of any financial difficulties that patients incurred. We thought relationships could be drawn from patients having financial problems arising from hospital policy regarding workers compensation.

This provided some precise data about many subgroups of people. By stating of symptoms, and the severity of the operative procedure, we should able to evaluate what information should be included, and not included, in the final brochure. All questionnaires were specifically for consenting adults, the names were kept anonymous to protect the rights of the patient, and the duration of questionnaire acquisition was limited to 90 days, by our choice.

Chapter 5: Results and Analysis

In this chapter we discuss the responses obtained from the questionnaire distributed at the UMMH. Upon review of the filled-out questionnaires, we were able to make a number of generalizations about spinal fusion patients. Although our questionnaire did not leave much room for patients to describe their experience, some added personal comments describing their experience with the procedure, as well as helpful tips that they would recommend to future patients. Overall, the comments heightened our awareness and gave us further insights into the patients' experience with spinal fusion.

5.1 Review of Patient History Results

In order for us to accurately interpret each patient response, the questionnaire began with a series of procedural and patient history questions, giving us a way to classify each patients questionnaire. The questions dealt with the patients condition, the type of procedure performed, the surgical approach used to access the spine, the type of fixation used to stabilize the spine, and other issues to establish an adequate patient history. We determined in advance that a doctor or nurse should fill out a portion of the patient history section, since patients may not have been able to answer some of the more technical questions.

5.1.1 Nurse/Physician Responses

The first question of this section asked: "what was the patients condition?" As can be seen in figure 4-1, the patients sampled had a variety of spinal disorders. Twenty eight percent of the patients surveyed had degenerative disc disease.

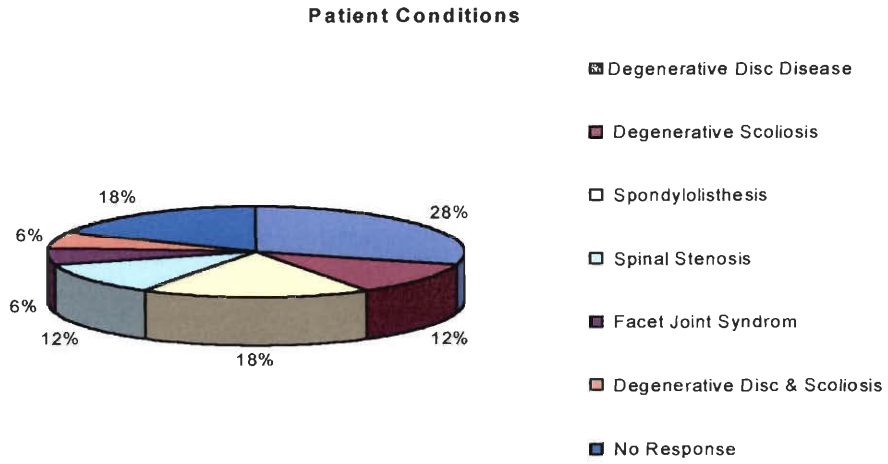


Figure 4-1.

Degenerative disc disease is the most frequent disorders to occur in patients who are facing a spinal fusion, therefore it is not surprising that it took up the largest percentage.

Spondylolisthesis and patients who did not respond to this section of the questionnaire, were tied for second, claiming 18% of the sample. The remaining distribution of patient disorders were what would be expected from a random sample of spinal fusion patients, since these disorders are less frequent than degenerative disc disease and spondylolisthesis. Degenerative scoliosis and spinal stenosis, each claimed 12% of the patients surveyed. Facet joint syndrome, and degenerative disc disease combined with scoliosis, rounded off the rest of survey, with each claiming 6%.

The second question on the survey dealt with the type of spinal fusion that the patient had done. The possible answers were laparoscopic, open, or other. As can be seen in the pie chart below, 24% of the patients had the laparoscopic procedure and 58% had the open procedure. The remaining 18% did not respond.

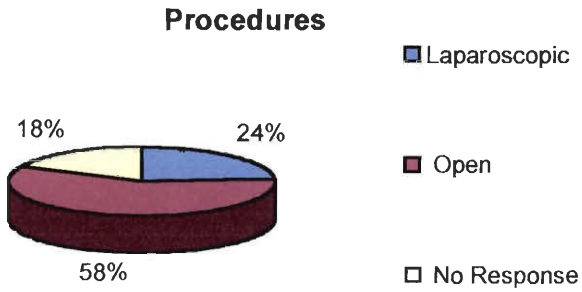


Figure 4-2

We were quite pleased to have seen such a large percentage of spinal fusion procedures performed laparoscopically, since this will give us many responses from the perspective which we hold as the most valuable. However, we are not discrediting the responses from the patients who had the open procedure, since their responses added some valuable testimonials, as well.

The third question in the categorical section, dealt with the type of fixation device that was used to stabilize the spine during the fusion process. The anticipated responses were the BAK inter body cage, pedicle screw fixation, and other, for any type of fixation device that could have been used. As can be seen below in figure 4-3, both the pedicle screw and the BAK were tied with 31%. The BAK interbody cage is presently the only fixation device used during laparoscopic procedures, because of its

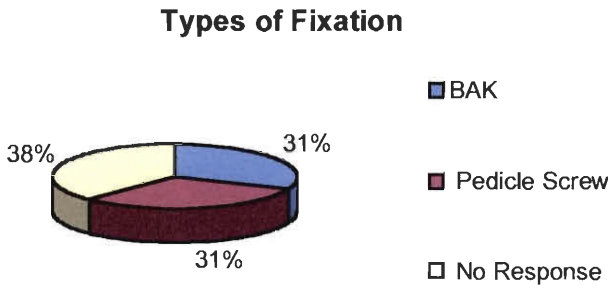


Figure 4-3

cylindrical geometry and lack of additional components, allowing it to be easily implanted through small incisions. One patient who had the open procedure also had the BAK interbody cage. It is not uncommon for doctors to use a BAK interbody fusion cage while doing an open procedure, since clinical studies have shown far better results with the BAK over the traditional pedicle screw fixation. However, pedicle screw fixation is still used today in patients where BAK use is not advised. The safety and effectiveness of the BAK has not been established in patients with the following conditions: gross obesity, three or more levels to be fused, symptomatic cardiac disease and greater than grade one spondylolithesis[27, 39].

The last question from this section, asked what surgical approach was used to access the spine. Fifty-nine percent of the patients had their spine accessed anteriorly. Posterior procedures made up only 6% of the sample. The remaining 35% did not respond to this question.

These four questions of the questionnaire were left blank, more so than any other section of the questionnaire. The nurse or physician was probably busy and forgot to fill in this section, before they handed it to the patient. Not having this information was

detrimental to our ability to categorize some of the response; however, we were able to extract some useful information, from comments made throughout the questionnaire.

5.1.2 Patient Responses

This section was a continuation of the patient history section begun in the previous section, the only difference being that this section is actually filled-out by the patient, as is the case for the rest of the questionnaire.

The first question from this section asked patients how long they had their condition. On average, patients had their condition for two and a half years. This average is not surprising, since in the majority of cases, a spinal fusion is not performed as soon as symptoms appear. Except for extreme degenerative conditions or injury, spinal fusion is intended for patients who have been through conservative treatment for at least 10 months without results [12, 27, 30, 39,41, 43].

Eighty two percent of the patients indicated that this procedure was their first spinal fusion and 18% indicated that it was not. Of the 18% who had a previous fusion, all of these were traditional opens, with pedicle screw fixation. One of these re-operations was performed using the laparoscopic techniques. This statistic brings up the fact that spinal fusions of the past have not been perfect. These less-than perfect results are typically because of misdiagnosis or failure of fusion to take place. Doctors believe that the primary reason for persistent back pain after surgery is the lack of bone fusion, which has been the driving force behind the development of interbody fusion cages[12, 25, 43, 39] (section 2.3.3).

In hindsight, it would have been useful to know what vertebral level was operated on during the procedure and how many levels were fused. A patient with a fusion at L5-

S1 may have less postoperative discomfort than a patient who was fused at L3-L4, since the vertebral space at L5-S1 is easier to access than L3-.L4. Similarly, a patient who had undergone a multiple level fusion would have more post-operative pain and would heal slower, than a patient who only had a single level fusion, due to the increase in complexity.

5.2 Interference with Daily Living

The next three questions asked patients how often back pain interfered with their daily activities before surgery. The first question asked: "how often does your back pain prevent you from doing activities that require strength or flexibility?" The possible

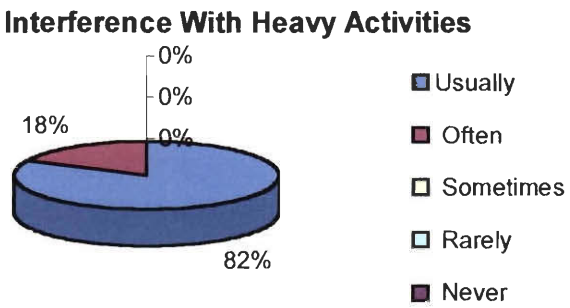


Figure 4-5

choices indicated the frequency of interference were as follows: usually (more than ¾ of the time), often (between ½ and ¾ of the time), sometimes (between ¼ and ½ of the time), rarely (less than ¼ of the time) and never. The responses from this question are shown in figure 4-5. Nearly all patients (82%) circled 'Usually', the most extreme

response on the questionnaire. The remaining 18% indicated 'Often' the second most extreme response on the questionnaire. Some patients even wrote in their-own response indicating greater frequency, such as 'all the time'. Although, there wasn't a need to write in 'all the time' ('usually' covered 'more than ¾ of the time'), it is clear that patients who have had spinal fusion procedures could not perform heavy activities before surgery.

The second question from this group asked: "How often does your back pain prevent you from doing light to moderate activities, such as washing dishes, cooking, light cleaning, going up stairs, etc?" Responses to this question are shown in figure 4-6.

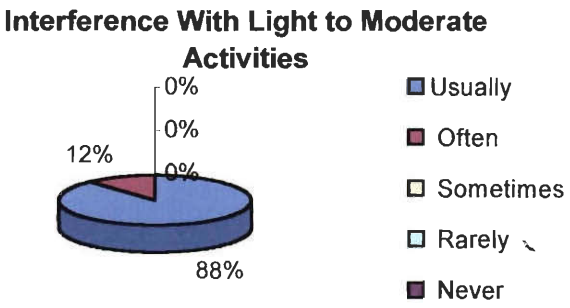


Figure 4-6

The response to this question yielded the same distribution as the previous question, 82% circled 'Usually' and 18% circled 'Often'.

The third question had the same choices as the previous two, but asked: "how often did your back pain interfere with your social life?". As can be seen in the figure

below, 64% of the patients circled 'Usually', 18% circled 'Often', and the remaining 18% circled 'Sometimes'. Indicating that the majority of spinal fusion patients have back pain that interferes with their social life.

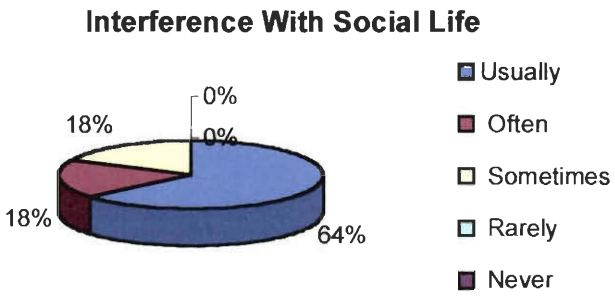


Figure 4-7

The last question in this section asked patients: "how far were you able to walk without resting due to back problems?" As with the previous three questions, back pain kept the majority of patients from carrying out this activity. Eighty percent of the patients only could only walk one or two blocks before their surgery.

Each question from this section surveyed different physical and social activities requiring varying degrees of exertion. Upon review of the results, it is quite clear that patients could not perform their daily activities because of back pain, whether playing golf, washing dishes or visiting friends. These responses will be useful to describe the common restrictions and discomforts that most patients have before spinal surgery. It may be comforting for a patient to know that other people have had the same restrictions, and have found relief in spinal fusion.

5.3 Degree of Pain Before and After Surgery

Above all, patients want relief from their debilitating pain. Therefore, we felt the need to ask patients to rate their level of pain, before and after the surgery. Patients rated their pain from one to six, one being the least amount of pain and six being the most painful. We also asked patients the type of medication that they took before and after surgery.

The average pain level before and after surgery, for the entire sample of patients was 5.55 and 3.15, respectively. It is clear from the responses that patients had a significant amount of pain before surgery. Although patients' pain was decreased from 5.55 to 3.15, patients still had a moderate degree of discomfort after the procedure.

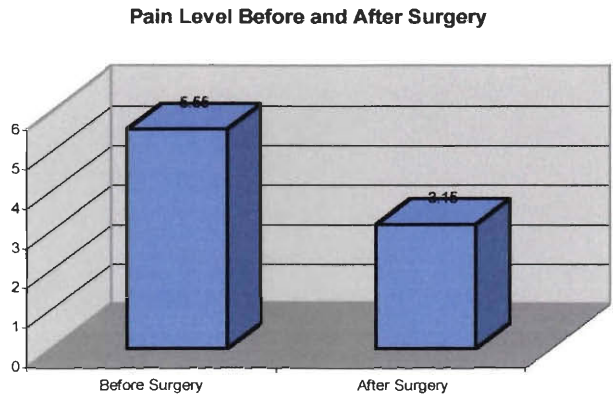


Figure: 4-8

Since, the recovery time from a spinal fusion is dependent on the procedure performed, it will be clearer to break down the data even further. The average pain level before and after surgery, for patients who had the procedure performed laparoscopically, was 5.7 and 2.25, respectively. Patients who had the laparoscopic procedure indicated slightly higher pain levels before the surgery, and lower pain levels after the surgery,

compared to the entire sample of patients. These results are consistent with reports on the benefits of minimal invasive spinal surgery, decreased post-operative pain due to less tissue trauma. However, these pain levels are dependent upon each patients interpretation. Instead, we should have asked questions relating to postoperative activity levels, as this would have been a less subjective response to measure.

Although, patients who had the laparoscopic procedure had slightly lower post-operative pain levels than patients who had the open procedure, patients still had discomfort after the surgery. As with any procedure, the level of pain is going to be more significant immediately after the procedure, and steadily decrease as soft tissues heal and fusion begins to take place. The questionnaire was distributed to patients returning for their first postoperative visit, approximately two weeks after the surgery. Therefore, we can say that the pain level, two week's port-op, is lower for laparoscopic patients than patients who had the open procedure performed. However, we don't have data to show how the pain level changed with time.

Perhaps the most useful input came from a patient who described a great deal of pain associated with any twisting motions. This patient also described a great deal of difficulty with getting in and out of the car, when leaving the hospital for the first time. This kind of input is what we were looking for in the first place, descriptions of the surgical procedure from the perspective of the patient. However, we had a great deal of difficulty, in obtaining this sort of response.

Patients were asked what kind of pain medications they took before and after surgery, as well as the dosage. We found that the majority of patients took a number of different pain medications, such as vicaden, ibuprofen, and predizone before and after

surgery. Most patients said that they took these medications as often as needed, twice a day, and some patients simply said that nothing helped the pain.

5.4 Number of Smokers Surveyed

The majority of the patients surveyed were not smokers. We were initially concerned with knowing this, because smoking decreases the rate of bone fusion, which significantly decreases the chances of a successful recovery and is a source of prolonged pain after surgery. We compared the number of patients that had just undergone their second spinal fusion, and found that one out of the three had been a smoker. Out of the patients who had a second spinal fusion, only one of them was a smoker. It's impossible to determine, based on our information, if this was a direct result of smoking or some other cause. However, it will still be worth mentioning the effects that smoking has on the patients' recovery, since the increase in postoperative complications has been well documented for smokers.

5.5 Responses to Procedural Questions

The last section of the questionnaire addressed issues that revolved around the procedure itself.

All patients surveyed said that their doctor discussed the possible complications with them, and only 10% of the patients indicated that they had questions or concerns about the surgery, but no one identified what their concerns were.

Next, when asked: "what helped to answer your questions and relieve your concerns?" 72% replied a conversation with their doctor or nurse, 5% answered an instructional video, and 23% answered an instructional brochure.

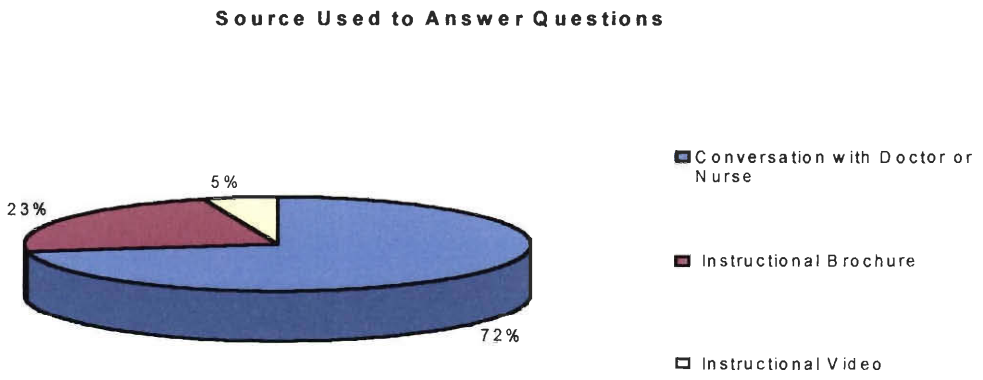


Figure 4-9

Out of the 24% of patients, who said that an informational brochure relieved their questions and concerns, all of these patients had the traditional open procedure performed. Conveying to us that there were in fact patients whose questions and concerns were answered with a brochure, and that there is a lack of this form of information for patients who are having laparoscopic procedures.

The majority of patients were satisfied with the results of the procedure, and did not express any complaints. Three patients indicated that they would have to undergo another procedure, but that they were satisfied with results of the last one. Of the few that were not satisfied, they did not give any reasons for their dissatisfaction. We were hoping to a great deal of patient input for this question. This was one of the few

questions where we did not give answers to choose, anticipating that patients would elaborate on this question. However, no one stated the reason for their dissatisfaction, even though, they were dissatisfied. All of the patients who had the laparoscopic procedure were satisfied, and did not indicate the need for another surgery.

One patient encountered difficulty in paying for the procedure, and this patient indicated the importance of contacting your insurance company to make sure that the hospital stay has been approved. Also there were five patients who indicated that some of their bills were being covered by workman's compensation.

Chapter 6: Design and Implementation of Brochure

Initially, we set out to develop a patient brochure that would include the most recent innovations in spinal fusion: interbody fixation devices, laparoscopic surgery, and the muscle sparring approach to open surgery, since present patient brochures do not include descriptions of these techniques. After doing extensive background research on the recent innovations in spinal fusion and conducting a questionnaire, we have gathered enough information to put together a patient brochure.

As stated earlier, the most important aspect in presenting these topics to patients is to do so in a language that any patient can understand. Thus, the first step in producing the brochure was to determine what information is the most critical to give to patients, and portray this information in an easy to understand and positive context.

We felt that the brochure should begin with a brief description of lower back pain and when patients should consider having spinal surgery. As the results from the questionnaire indicated, lower back pain interfered with nearly every aspect of the patient's life. Therefore, we want the reader of the brochure to know that spinal fusion is intended for people whose back pain plays a controlling role in their life. Next, a brief statement regarding the treatment process should be given, to get the patient focussed in on the most important thing, recovery. While, indicating the importance of playing an active role during the recovery process.

To give the patient an understanding of how their spine works and the problems that affect it, the next section will consist of the anatomy and physiology of the spine. This section will be a brief summary of the information described in the anatomy and physiology section of the background research. After describing the structure and basic

functions of spine, we felt that it would be appropriate to discuss the diagnosis process. This would prepare the patient for things to come, or it could serve as a way to measure the treatment they have received. Although, this brochure has been geared towards spinal fusion patients, there will be a brief section on conservative treatments, as all spinal fusion patients should go through a conservative treatment before being candidates for surgery.

Next, we will mention the procedures themselves; laparoscopic, muscle sparing, and the traditional open, and explaining how each is performed. Thus, giving the patient a feel for the procedure they are going to face. We want to make it clear to the patient, the benefits of laparoscopic surgery, while indicating the need for other procedures as well.

It will be important to have a section that describes the experience following surgery. We will include the comment from the patients' response on the questionnaire, describing the pain associated with any twisting motions following the procedure. This will give the patient an indication of the discomfort they can expect, and let them know that even though these procedures are minimally invasive, there is still a great deal of discomfort initially. Perhaps most importantly, we will explain the importance of making healthy back habits a way of life, to maximize the results of the procedure and enjoy a life with minimal back pain.

Patient Brochure

Understanding Lower Back Pain and Treatment

A Reference Guide

Spinal Fusion:
Understanding Lower Back Pain and Treatment

Today, lower back pain disables millions of Americans. Most cases of lower back pain are resolved without the need for surgery, however, when conservative treatments fail, spinal surgery may be beneficial.

Recent innovations in spinal fusion surgery now offer patients better results and quicker recoveries. Spinal surgery is an important step, one that can play a crucial part in your overall treatment and recovery.

Lower back problems

The pain and disability from severe lower back problems can affect every aspect of your life. Symptoms may prevent you from doing your job, prevent you from performing daily activities, and affect your relationship with your friends and family. However, there is a solution.

A Well Informed Patient

Know your spine

The quickest way to recovery is knowing what the problem is. By understanding how your spine works and the problems that affect it you can begin to take an active role in your recovery.

Understand your diagnosis and treatment

Treatment begins with a medical evaluation and accurate diagnosis. Treatment options include conservative management or spinal fusion surgery. If surgery is the recommendation of your doctor, understanding the technique will help you mentally prepare for it.

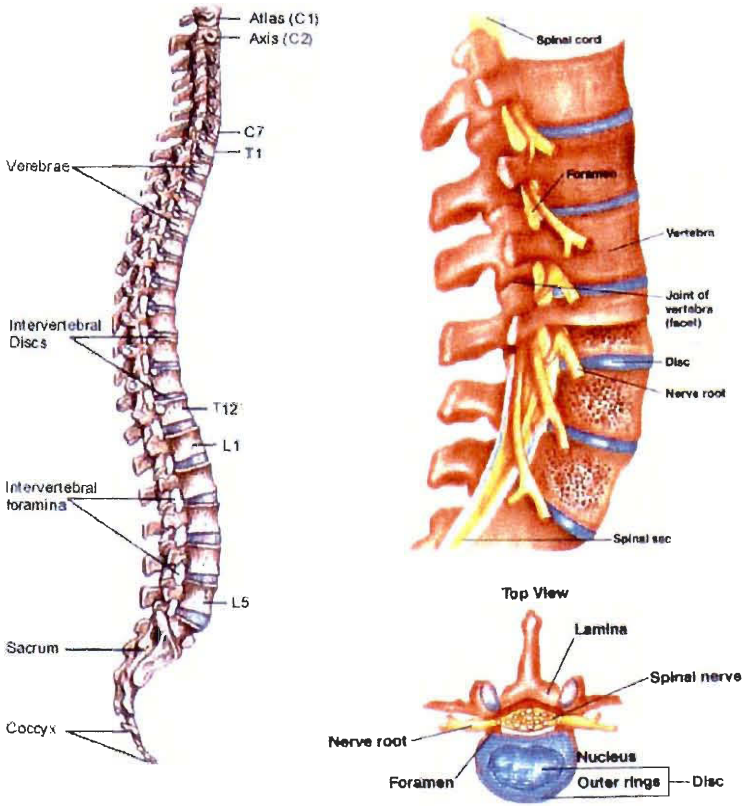
Take an active role in recovery

Your time and effort after surgery determines the success of your recovery. Make back health a habit for life by stretching properly and using your back correctly. Proper lifting techniques and proper back management is the way to a full recovery.

Learning about your spine

To understand why you may need spinal surgery and how to protect your back before and after surgery, you need to learn about your spine and how it functions. A healthy spine protects the spinal chord and supports the body while allowing it to move freely and without pain. Its vertebrae and discs between them are aligned in four curves. (See Figure 1) These curves are kept in a balanced position by strong flexible muscles. Due to injury or the natural aging process, certain spinal problems cause discs or bones to press on the roots of the spinal nerves causing symptoms such as pain, stiffness, tingling and numbness.

Figure 1 - Your Spine



Diagnosis

Lower back pain can have many causes, and not all of them originate in the spine. In order for your doctor to prescribe treatment, they will need an accurate diagnosis. The physician should perform a thorough medical evaluation to prescribe the appropriate treatment, consisting of a medical history, a physical exam, and some diagnostic tests.

Figure 2 - Diagnostic Tests

MRI

CT Scan

X-Ray

Medical History

Medical history will include a person to person interview about your lifestyle and any previous medical treatments. The interview will also include questions about your work habits, daily activities, nutritional diet, smoking habits, and medication you may be taking.

Physical exam

The physical exam will consist of your doctor examining your spine in several positions: sitting; standing; lying; and moving. The physician may ask you to do some simple movements to determine some causes of pain. There may be some leg movements, extensions, range of motion tests, and some flexibility tests. Your doctor will also check for weakness, numbness, and reflexes.

Diagnostic tests

Some diagnostic testing can be X-rays, or you may be asked to have an MRI, and, or a CT (Cat) scan. This will provide your doctor some valuable information that otherwise, the physician could not know. (See Fig 2)

Treatment

Some conservative (non-surgical) treatments may help alleviate pain and could very well prevent surgery. Your back may heal by itself if a combination of rest, medication, physical therapy, and a back brace is used. Your doctor can prescribe each of these options, and can tailor a treatment program that will work just right for you. When surgery has been prescribed, knowing the surgical techniques may help you with your mental preparation.

Surgical Techniques

Traditional Open Surgery
This method is historically the most common of the surgical techniques. In an open procedure extensive layers of muscle are stripped from the bone and are pulled open, and internal organs are manipulated more forcefully than in any other spinal surgery technique. Average hospital stay is two weeks. Patients may typically return to work within three to six months depending on the physical nature of their job.

Muscle Sparing Approach
This is a modified version of traditional open surgery using much of the same equipment but makes a small incision through the abdominal muscle. This procedure claims to offer patients shorter hospital stays and quicker recoveries than the traditional open surgery. However, along with these results comes significant muscle splitting incisions, a four to six day hospital stay and a loss of employment for four to six weeks after the procedure.

Minimal Invasive Surgery
The laparoscopic approach to surgery uses four to five small incisions, approximately one centimeter each, instead of one large incision to access the affected area. The laparoscope (a thin telescope like tube) is then inserted through one incision, and displays a magnified image on a TV screen in the operating room. Using the laparoscope as a guide, the surgeon uses the other incisions to insert special tools to work on the affected area. A consultation with your doctor will determine if this type of surgery is applicable for your condition. Laparoscopic spinal surgery is not advised for patients who have had previous abdominal surgeries, pelvic infection and suffer from obesity. The average hospital stay with laparoscopic surgery is between two and four days. The patient can typically return to light work in three to four weeks.

Bone Grafts

Currently, spinal fusion usually involves harvest of bone (autograft) from the iliac crest (pelvis).

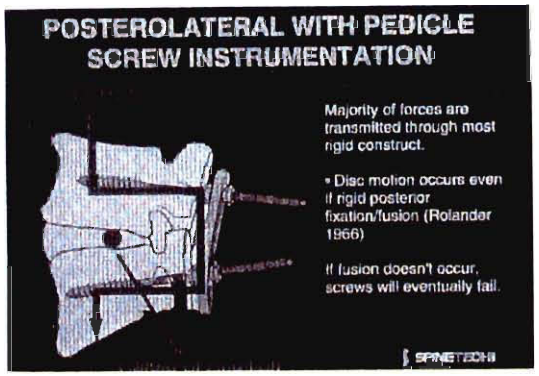
Autogenous iliac crest bone graft is currently the gold standard graft material for lumbar fusion. Most surgeons accept that fresh autogenic bone provides the best available graft material, although surgical harvesting of autogenic bone from the iliac crest may have complications. Even in the hands of experienced spine surgeons, donor site pain may be present in as many as one third of patients.

Fixation

Until recently, fixation devices were comprised of screws or bolts, which were used to secure cables, rods, or plates to the spine. New instrumentation has been developed.

Pedicle Screw Instrumentation
Internal fixation devices, such as pedicle screws (see Figure 3), were incorporated to improve on fusion rates. The mechanical reality of spinal fusion is that a bone graft alone is not enough to fully support the load seen by the lumbar spine. Pedicle screw instrumentation has been the "gold standard" to improve alignment, stability and fusion rates for many years, but less than perfect and unpredictable results have led to the development of new techniques in vertebral fixation.

Figure 3 - Pedicle Screw Fixation



Interbody cages
Interbody cages, can be square or cylindrical tubes, which fit directly in the vertebral space securing both the upper and lower vertebral spaces. The BAK interbody fusion cage, produced by Spine-Tech Inc., was the first interbody fixation device developed and is shown in the figure below (see Figure 4).

Figure 4 - BAK Fusion Cages

These, hollow, porous titanium devices are square threaded and slightly tapered. The surgical procedure involves implanting two threaded cylinders into the disc space at the affected vertebral level to restore normal disc height. Perhaps most importantly, the procedure required to implant these devices is significantly less invasive than the pedicle screw instrumentation. It should be noted that this device set the stage for laparoscopic spinal procedures.

Proximity interbody cage
In addition to the cylindrical BAK, a square interbody cage has been developed, called the Proximity. The biomechanics of the square Proximity fusion cages support a larger area of vertebral disc space and offers better stability, than the BAK. However, the Proximity's present internal structure does not allow for as much bone graft to be implanted, as the BAK.

Recovery and You

The choice of non-surgical or surgical methods, type of surgery and type of bone graft fixation is up to you with consultation from your doctor. Ultimately, your goal is to become active as soon as possible, and to gradually increase your activity while protecting your back to give it time to heal. Maintain a balanced aligned position of comfort at all times. Even when resting and getting out of bed. Soon, you will progress to a reclined and supported position of comfort, then to standing, and then to walking. It's up to you and the discomfort level you have to decide when it's right for you to progress to the next phase.

Follow your doctors' advice about daily and personal activities. Continue to follow a program of exercise and rehabilitation. Your doctor will prescribe treatment for physical therapy, and be sure to follow your healthcare professional's instructions about exercise.

Be sure to keep follow up appointments with your doctor so they can keep an accurate account of your progress, and prescribe any additional treatment if needed. Ask your doctor when you can safely return to daily routines like driving, and getting back to work.

It's up to you to continually work to improve and maintain the health of your back from this day forward. Along with your doctors monitoring, and advice, your back program will help you to lead a life without back pain.

Wishing you success!

Credits: Krames Communications
Consultants: Arthur White, MD; Ann Pivarski, OPA; Marie Shouldice, RN
Contributors: Susan Carpenter, PT; Perry L. Cohn, MD; Scott H. Kitchell, MD

Prepared by Kevin J. McNamara and Matthew J. Skladany

Chapter 7: Future Recommendations

As the results from the questionnaire have shown, it was difficult to obtain qualitative descriptions from the questionnaire we used. We were hoping to obtain patient accounts that would describe the procedure from a perspective that only a patient could provide. Especially, from the patients who had the laparoscopic procedure, since we were putting together a brochure for that would include this new technique. We obtained a few helpful comments, but for the most part we found that patients did not want to elaborate on their responses. A number of patient accounts, describing the procedure, would add a valuable dimension to any piece of literature intended for patients.

The difficulty in obtaining this sort of response was that patients did not elaborate on any of their answers. Patients answered the questions that had multiple choice answers, however, did not reply to any of the questions that required descriptive responses. In hindsight, we should have asked more questions about the time period, immediately after the surgery to the time of their two-week follow-up visit. It would be a good idea to focus in on questions from this time-period, because this is probably the most difficult time during the recovery process. It would take a great of trial and error to determine what types of questions give the response that your looking for, since patients do not respond well to questions where they have to write a descriptive answer.

Besides obtaining better qualitative data, bone morphogenic proteins (BMPs), may open new doors in treating spinal fusion, and offer an entirely new area to take-up in a brochure. The long- term goal of BMP, is to eliminate surgery altogether (see section 2.6 for more on BMPs). The plan is to be able to induce bone growth with just a dosage of BMP. The patient could walk into the doctors office, get a shot of BMP and their

spine will fuse without surgical intervention. This sort of treatment is in the future, although, BMPs have been shown to increase the rate of spinal fusion in monkeys. Tests on humans, are in the process of being conducted, and shouldn't be too long before it is used in humans to increase the rates of bone fusion.

Another possible area of future research would be to create a web-site for spinal fusion patients. We were faced with dilemma when putting together our brochure: we had a lot of information that was too technical to be understood by everyone. It was our intent to produce a brochure that could be distributed at the doctor's office, and be understood by all patients. However, we also had a lot of information that went into a great deal of technical detail that some patients may want to know. Although, some of the information would be too much for some patients, those that are inquisitive enough could go to the web-site and find out some of the more technical information.

Glossary

Abduction: <anatomy, neurology> Movement of the limbs toward the lateral plane or away from the body.
Acute: Having a short and relatively severe course.
Adduction: **<anatomy, orthopaedics>** Movement of the limbs toward the medial plane of the body or toward the axial line of the limb.
Adjacent: Lying near, close, or contiguous; neighboring; bordering on
Allogenic: <genetics> Another term for being genetically dissimilar.
Ambulatory: able to walk about and not bedridden
Analgesics: Agents that relieve pain without causing loss of consciousness.
Anesthesia: Loss of normal sensation or feeling.
Annulus: Ring like structure.
Anterior <anatomy> Toward the front or in front of.
Anti-inflammatory: counteracting or suppressing inflammation.
Arthrodesis: <orthopaedics> The surgical immobilisation of a joint (joint fusion).
Autogenous: <biology> Self-generated; produced independently.

Bladder: A membranous sac that serves as a reservoir for urine.
Bone morphogenetic protein: <protein> Activity derived from bone that induces the formation of cartilage and bone in vivo. Seven bone morphogenetic proteins have been described, BMP 1 being the only one not in the TGF beta superfamily. BMP 3 was formerly called osteogenin. Acronym: BMP
Bowel: A general term that includes the small and large intestine.

Cancellous bone: Adult bone consisting of mineralised regularly ordered parallel collagen fibres more loosely organised than the lamellar bone of the shaft of adult long bones. Found in the end of long bones.
Cartilage: <pathology> Connective tissue dominated by extracellular matrix containing collagen type II and large amounts of proteoglycan, particularly chondroitin sulphate.
Cautery: The application of a caustic substance, a hot instrument, an electric current, or other agent to destroy tissue.
Cervical: <anatomy> Pertaining to the neck or to the neck of any organ or structure.
Cervix: the lower and narrow end of the uterus, between the isthmus and the ostium uteri.
Coccyx: <anatomy> The last bone of the spinal column, sometimes referred to as man's vestigial tail. The last portion of the vertebral column just below the sacrum.
Collagen: <protein> The protein substance of the white fibres (collagenous fibres) of skin, tendon, bone, cartilage and all other connective tissue, composed of molecules of tropocollagen, it is converted into gelatin by boiling. Collagenous pertaining to collagen, forming or producing collagen.
Contraindication: Any condition, especially any condition of disease, which renders some particular line of treatment improper or undesirable.
Cortical: <anatomy> Pertaining to or of the nature of a cortex or bark.
Cutaneous: <dermatology> Pertaining to the skin, dermal, dermic.

Cysts: Any closed cavity or sac, normal or abnormal, lined by epithelium, and especially one that contains a liquid or semisolid material.

Degenerative disc disease: <radiology>: narrowing of disc space; osteophytes; bone sclerosis, disc calcification, vacuum disc phenomenon; MRI:endplate changes, Type I (4%): decreased signal on T1; increased signal on T2; vascularised fibrous tissue, Type II (16%): increased T1; isointense T2; local fatty replacement of marrow, Type III: decreased T1; decreased T2; advanced sclerosis sequelae: disc bulging, disc herniation, disc sequestration, spinal stenosis narrowing of disc space.
Depression: <psychiatry> A mental state of depressed mood characterised by feelings of sadness, despair and discouragement
Diagnostic: Refers to something that is used to determine the cause of an illness or disorder.
Disease: An alteration in the state of the body or of some of its organs, interrupting or disturbing the performance of the vital functions, and causing or threatening pain and weakness
Dysesthesia: (dysaesthesia), An unpleasant abnormal sensation, whether spontaneous or evoked.
Dysfunction: Disturbance, impairment or abnormality of the functioning of an organ.

Endoscope: <instrument> An expensive and usually highly flexible viewing instrument with capabilities of diagnostic (biopsy) or even therapeutic functions through special channels.
Endoscopy: <procedure> The visual inspection of any cavity of the body by means of an endoscope.
Endotracheal intubation: The placement of a flexible plastic tube into the trachea for the purpose of ventilating the lungs.
Epithelium: <pathology> The covering of internal and external surfaces of the body, including the lining of vessels and other small cavities. It consists of cells joined by small amounts of cementing substances. Epithelium is classified into types on the basis of the number of layers deep and the shape of the superficial cells.
Erector: <anatomy> A muscle which raises any part.
Extensor: <anatomy> A muscle which serves to extend or straighten any part of the body, as an arm or a finger; opposed to flexor.
Extremity: <anatomy> A limb, an arm or leg (membrum), sometimes applied specifically to a hand or foot.

Facet: <anatomy> A smooth circumscribed surface; as, the articular facet of a bone.
Femoral: <anatomy> Pertaining to the femur or to the thigh.
Femur: <anatomy> The large bone in the thigh that articulates with the pelvis above and the knee below.
Fibreoptics technology: Uses thin strands of glass or plastic to transmit light (along their length through internal reflection) for imaging.

Fibrosis: The formation of fibrous tissue, fibroid or fibrous degeneration
Flank: <anatomy> The posterior part of the body below the ribs abd above the ilium (upper portion of the pelvis).
Foramen: <anatomy> A small opening, perforation, or orifice.

Graft: <surgery> A portion of living tissue
Gynecologist: <specialist> A medical doctor who specialises in gynecology and diseases affecting the female reproductive system.
Hematoma (haematoma): <haematology, pathology> A localised collection of blood, usually clotted, in an organ, space or tissue, due to a break in the wall of a blood vessel.
Herniated disk: <orthopaedics> A condition that results in the abnormal protrusion (bulging), herniation or prolapse of a vertebral disc from its normal position in the vertebral column. The displaced disc may exert force on a nearby nerve root causing the typical neurologic symptoms of radiating pain (to an extremity), numbness, tingling and weakness. Recurrent episodes of severe back pain are common.
Herniation: <anatomy> Bulging of tissue through an opening in a membrane, muscle or bone.
Hyaline: <cell biology> Clear, transparent, granule free, as for example hyaline cartilage and the hyaline zone at the front of a moving amoeba.
Hyperesthesia (hyperaesthesia): <neurology, physiology> A neurologic symptom where there is an unusual increased or altered sensitivity to sensory stimuli.
Hypochondria: <medicine> Hypochondriasis; melancholy; the blues.
Hypochondriasis: **<psychiatry> A mental disorder characterised by a preoccupation with bodily functions and the interpretation of normal sensations.**
Hysteria: <medicine> A nervous affection, occurring almost exclusively in women, in which the emotional and reflex excitability is exaggerated, and the will power correspondingly diminished, so that the patient loses control over the emotions, becomes the victim of imaginary sensations, and often falls into paroxism or fits.

Ileus: <gastroenterology, surgery> An obstruction of the intestines.
iliac crest: <anatomy> The hip bone in which a large quantity of bone marrow is concentrated.
Iliac vein: A vein on either side of the body which is formed by the union of the external and internal iliac veins and passes upward to join with its fellow of the opposite side to form the inferior vena cava.
Ilium: <anatomy> The upper and largest, part of the bony pelvic girdle (iliac wing). The ilium articulates on its inner aspect with the sacrum (sacroiliac joint).
Implants: Artificial substitutes for body parts
Incontinence: <gastroenterology, urology> The inability to control excretory functions.
Inferior: <anatomy> Situated below another structure.
Inflammation: <pathology> A localised protective response elicited by injury or destruction of tissues, which serves to destroy, dilute or wall off (sequester) both the injurious agent and the injured tissue.
Insufflation: <medicine> The act of breathing on or into anything; especially: The act of blowing (a gas, powder, or vapor) into any cavity of the body.

Internal fixation: The use of internal metal plates, screws or rods to stabilise bone fragments. A procedure used to correct serious orthopaedic bone fractures that cannot be stabilised by casting or splinting.
Intervertebral: <anatomy> Situated between two contiguous vertebrae.
Intestine: <anatomy, gastroenterology> This is a general term often used to describe both the small and large intestine.
Intraoperative complications: Disorders affecting patients during surgery. They may or may not be related to the disease for which the surgery is done. They may or may not be direct results of the surgery.

Laceration: A torn, ragged, mangled wound.
Laminectomy: <procedure, surgery> A surgical procedure which is designed to relieve pressure on the spinal cord or nerve root that is being caused by a slipped or herniated disk in the lumbar spine.
Laparoscopy: <procedure> A surgical procedure in which a tiny scope is inserted into the abdomen through a small incision
Lumbar: <anatomy> Pertaining to the loins, the part of the back between the thorax and the pelvis.
Lumbosacral: <anatomy> Of or pertaining to the loins and sacrum; as, the lumbosacral nerve, a branch of one of the lumber nerves which passes over the sacrum.
lymph node: <anatomy> Small bean-shaped organ made up of a loose meshwork of reticular tissue in which are enmeshed large numbers of lymphocytes, macrophages and accessory cells located along the lymphatic system.

Magnetic Resonance Imaging: A special imaging technique used to image internal stuctures of the body, particularly the soft tissues. An MRI image is often superior to a normal X-ray image. It uses the influence of a large magnet to polarize hydrogen atoms in the tissues and then monitors the summation of the spinning energies within living cells. Images are very clear and are particularly good for soft tissue, brain and spinal cord, joints and abdomen. These scans may be used for detecting some cancers or for following their progress. Acronym: MRI
Mesenchyma: <biology> The part of the mesoblast which gives rise to the connective tissues and blood.
Mesoblast: <biology> The mesoderm. The cell nucleus; mesoplast.
Morbidity: A diseased condition or state, the incidence of a disease or of all diseases in a population.
Morphology: <study> A study of the configuration or the structure of animals and plants.
Musculature: The muscular apparatus of the body or of any part of it.

Neoplasm: <oncology, pathology> New and abnormal growth of tissue, which may be benign or cancerous.
Neural: Situated in the region of the spinal axis

Neurologic: <anatomy> Pertaining to neurology or to the nervous system
Neurovascular: A term that pertains to both the neurologic and vascular structures

Obesity: <clinical sign> An increase in body weight beyond the limitation of skeletal and physical requirement, as the result of an excessive accumulation of fat in the body.
Oblique: Not erect or perpendicular; neither parallel to, nor at right angles from, the base; slanting; inclined.
Ossification: <orthopaedics> Pathology> The formation of bone or of a bony substance, the conversion of fibrous tissue or of cartilage into bone or a bony substance.
Osteo-: <prefix> A combining form from the Greek word for a bone.
Osteogenetic: <physiology> Connected with osteogenesis, or the formation of bone; producing bone; as, osteogenetic tissue; the osteogenetic layer of the periosteum.
Osteogenic: <physiology> Osteogenetic.
Osteoporosis: <pathology> A reduction in the amount of bone mass, leading to fractures after minimal trauma.

Pathology: <study> The branch of medicine concerned with disease, especially its structure and its functional effects on the body.
Peritoneal: <anatomy> Of or pertaining to the peritoneum.
Peritoneum: <anatomy> The smooth serous membrane which lines the cavity of the abdomen, or the whole body cavity when there is no diaphragm, and, turning back, surrounds the viscera, forming a closed, or nearly closed, sac.
Perivascular: Situated around a vessel.
Phylogenetic: Relating to phylogenesis, or the race history of a type of organism.
Pneumoperitoneum (artificial): Deliberate introduction of air into the peritoneal cavity
Portal: A door or gate; hence, a way of entrance or exit.
Postero-lateral: situated back and at the side.
Post-mortem: After death; as, post-mortem rigidity. <medicine> Post-mortem examination, an examination of the body made after the death of the patient; an autopsy.
Posterior: <anatomy> Situated in back of or in the back part of or affecting the back or dorsal surface of the body. In lower animals, it refers to the caudal end of the body.
Proximity: The quality or state of being next in time, place, causation, influence, etc.; immediate nearness, either in place, blood, or alliance.
Pseudarthrosis: A pathologic entity characterized by deossification of a weight-bearing long bone, followed by bending and pathologic fracture, with inability to form normal callus leading to existence of the "false joint" that gives the condition its name.
Psoas muscles: A powerful flexor of the thigh at the hip joint (psoas major) and a weak flexor of the trunk and lumbar spinal column.
Pubis: <anatomy> The ventral and anterior of the three principal bones composing either half of the pelvis; sharebone; pubic bone.

Radiologic: Pertaining to radiology.
Radiology: <study> The study of X-rays in the diagnosis of a disease.

Ream: To bevel out, as the mouth of a hole in wood or metal; in modern usage, to enlarge or dress out, as a hole, with a reamer.
Rectus abdominis: A long flat muscle that extends along the whole length of both sides of the abdomen.
Retention: The persistent keeping within the body of matters normally excreted.
Retroperitoneal: <anatomy> Behind or posterior to the peritoneum.
Rheumatism: <medicine> A general disease characterised by painful, often multiple, local inflammations, usually affecting the joints and muscles, but also extending sometimes to the deeper organs, as the heart.
Rheumatoid: <pathology> Resembling rheumatism.

Sacroiliac joint: The joint between the sacrum and ilium and associated ligaments.
Sacral: <anatomy> Of or pertaining to the sacrum; in the region of the sacrum
Sacrum: <anatomy> The triangular-shaped bone lying between the 5th lumbar vertebra and the coccyx (tailbone). It consists of 5 vertebrae fused together and it articulates on each side with the bones of the pelvis (ilium), forming the sacroiliac joints.
Sagittal: <anatomy> Sagittal suture, the suture between the two parietal bones in the top of the skull
Scoliosis: <anatomy> A congenital lateral curvature of the spine.
Segmental: <anatomy> Of or pertaining to the segments of animals; as, a segmental duct; segmental papillae. Of or pertaining to the segmental organs.
Spinal fusion: A procedure that involves fusing together two or more vertebrae in the spine using either bone grafts or metal rods
Spinal stenosis: An abnormal narrowing of the spinal canal that may be either congenital or acquired.
Spinous: <anatomy> Spinous process of a vertebra, the dorsal process of the neural arch of a vertebra
Spondylolisthesis: Forward movement of one building block of the spine (vertebra) in relation to an adjacent vertebra.
Stylet: <surgery> An instrument for examining wounds and fistulas, and for passing setons, and the like; a probe, called also specillum.
Supplant: To remove or displace by stratagem; to displace and take the place of.
Suprapubic: <anatomy> Above the pubic bone.
Surgical: <surgery> Of, pertaining to or correctable by surgery.
Symptomatic: Pertaining to or of the nature of a symptom.

Transverse: Lying or being across, or in a crosswise direction; athwart; often opposed to longitudinal.
Tap: <mechanics> A tool for forming an internal screw, as in a nut, consisting of a hardened steel male screw grooved longitudinally so as to have cutting edges.
Trocar: <surgery> A stylet, usually with a triangular point, used for exploring tissues or for inserting drainage tubes, as in dropsy.
Thoracic: <anatomy> Pertaining to or affecting the chest
Trauma: Injury.

Umbilicus: <anatomy> The depression, or mark, in the median line of the abdomen, which indicates the point where the umbilical cord separated from the fetus; the navel.
Urologic: Pertaining to the practice of urology.
Urology: <study> A branch of medicine concerned with the diagnosis and treatment of diseases of the urinary tract and urogenital system.

Vascular: <physiology> Pertaining to blood vessels or indicative of a copious blood supply.
Vertebra: <anatomy> One of 23 bones (excluding the sacrum) in the cervical, thoracic and lumbar regions that comprise the spine. There are 7 cervical vertebrae, 12 thoracic and 5 lumbar vertebrae. The bottom of the spine is fused and forms the sacrum.
Vertebral: <anatomy> Of or pertaining to a vertebra.

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Appendix

An outline for the questionnaire;

We feel that a void exists in patient knowledge regarding spinal fusion surgery.
We conjecture that having personal patient accounts describing the surgery from the patient's perspective will help prepare other patients for their surgery.
First and foremost we needed to determine if and how it would be possible to approach patients, to acquire a first-hand description of spinal surgery. Therefore, the possibility of approaching patient's while in the hospital (pre or post operative), as well as patients waiting to have surgery and those who are undergoing physical therapy, were looked into. To increase the quantity of patient accounts, we sought out referrals to other medical facilities that deal with patients who have had (or are going to have) spinal fusion (i.e. rehabilitation clinics and other hospitals). We thought interviews would increase our rate of response and would eliminate waiting for replies. Perhaps most importantly, it would give us a chance to probe into areas of interest that we hadn't anticipated.
The down side of interviewing was that too much time would have been required for us to conduct them, patient confidentiality, and other legal problems associated with interviewing.
We decided to formulate a questionnaire that could be administered shortly after surgery. In our efforts to put forth an informative brochure to those patients who face spinal surgery, we felt this was a necessary and integral part of our data collection We thought an ideal time for patients to complete a questionnaire would be on their first follow-up meeting. The goal of our questionnaire was to obtain qualitative data from patients who have undergone spinal fusion surgery, and felt that with a concise questionnaire, we would be able to extract viable information specific to spinal surgery.
The most appropriate method for carrying out data collection.
I. Questionnaire that a nurse could give to a patient while recovering
-convenient - but run the risk of missing unanticipated & very important details of the surgery.

II. Personal interviews with patients. -increase our rate of response-eliminate the time waiting for a reply - probe into areas of interest that we hadn't anticipated - assure that we have well articulated responses

III. Mail previous patients. -decrease our chances of response - could be helpful to contact more people - still run the risk of missing unanticipated questions

Approaching patients
I. Pre or Post Operative
II. PT patients

Questionnaire for Spinal Fusion Patients

History

What is the diagnosis of your condition?

Degenerative Disk Disease Spinal Stenosis Spondylolisthesis
Degenerative Scoliosis Facet Joint Syndrome Disc Herniation

How long have you had this condition?

Are you a smoker? (Yes / No) If yes, how long?

Have there been previous family back/spinal problems? (Yes / No)

Procedural

What options did your doctor give you?

Did your doctor mention minimal invasive surgery? (Yes / No)

If so which technique: laparoscopic, minimally invasive open, muscle sparing technique? Other?

If laparoscopic spinal fusion was the surgery you had performed, did you have any specific concerns about this type of surgery? (Yes / No)

If you answered yes, what were they?

If a traditional open spinal fusion was the surgery you had performed, did you have any specific concerns about this type of surgery? (Yes / No)

If you answered yes, what were they?

If a minimal invasive open procedure was the surgery you had performed, did you have any specific concerns about this type of surgery? (Yes / No)

If you answered yes, what were they?

Personal

Have you spoken with anyone who has had this surgery before? (Yes / No)

Did the doctor discuss the possible complications with you? (Yes / No)

Have you had a second opinion? (Yes / No)

What drove you to your decision?

Pre-op

Did the doctor provide educational information to you regarding your condition and surgery? (Yes / No)

Was it helpful? (Yes it resolved all my questions / No I still had questions)

If you still had questions what were they?

Did you have issues that were unresolved? (Yes / No)

What kinds of pain medications were administered before surgery?

Did you understand all of the details of the pre-op experience provided by the nurses? (Yes / No)

What was your level of discomfort before the surgery (rating scale 1-5)?

Recovery / Post-Op

What was your level of discomfort immediately after the surgery (rating scale 1-5)?

24hours, 48hours, 72hours after surgery?

What pain medications were prescribed after surgery?

How long did your doctor say your recovery would be?

How accurate was this?

How long was your hospital stay?

What criteria had to be met before the patient can leave?

Did your recovery require home visits from nurses? (Yes / No)

Was Physical therapy prescribed? (Yes / No)

If so how many visits?

Insurance Issues

Did you encounter any difficulty paying for the procedure? (Yes / No)

Was your Health Insurance Provider reluctant to pay for anything? (Yes / No)

Did your Health Insurance Provider require a second opinion? (Yes / No)

Did you have to obtain a prior approval for this type of surgery? (Yes / No)

April 26, 1999

Department of Orthopedics
University of Massachusetts Memorial Hospital
55 Lake Avenue
North Worcester, MA 01605

Dear : Alice Shakman

Our Interactive Qualifying Project (IQP) is to develop, investigate, and report on a topic examining how science and technology interact with society. As you may know, many IQPs are performed at UMMH. The goal of our research is to produce an easy to read brochure that will educate the patient about a variety of newly developed and medically accepted techniques, as well as traditional surgical approaches to spinal fusion. This will benefit your department by helping patients make an informed decision before spinal fusion. A section on the anatomy and physiology of the spine will be included, along with the origin and nature of spinal disorders, and the different possibilities for treating them. Lastly, the brochure will give patients a description of pre and post-operative guidelines that should be followed to yield the most successful results possible.

So far, our information has come from medical journals, surgical videos, and personal interviews with doctors and nurses. We think the project now needs qualitative data describing the patient's experience with spinal fusion. We can get standard diagnostic & surgical information from the literature, but we want to find out, from first hand accounts, what it feels like to be a patient who is going to have or who has had a spinal fusion. For this reason, we have developed a short questionnaire for patients, so we can get further insight into what to include in our brochure.

As the attached questionnaire shows, we are not interested in the names of patients or their doctors. In fact, we anticipate that the questionnaire would be given to patients by a nurse and we will not know the patients identity. The results obtained from the questionnaire will be mentioned only in the aggregate of our project report, and will only be used to direct us in formulating the contents of the brochure. Our final report and the brochure will be handed into our advisors for grading on October 16, 1999 and will be on reserve in Gordon Library at WPI.

Thank you very much for your consideration in our most important endeavor. Please feel free to contact us if you have any questions or concerns.

Sincerely,

Kevin J. McNamara
(651-8189, kjmac@wpi.edu)

Matthew J. Skladany
(757-6980 skladany@wpi.edu)

A letter to the patient:

Thank you for participating in the following study on spinal fusion surgery. The questionnaire you are about to complete will allow students from Worcerster Polytechnic Institute to create a brochure explaining spinal fusion surgery, the procedure, the benefits and the effects.

Your participation is needed to assure that true accounts from real patients are recorded and used to prepare future patients. If you have any questions regarding this questionnaire, please ask the doctor or nurse who has been involved with your treatment.

Thank you again for your participation,

The Biomedical Engineering Students of Worcester Polytechnic Institute

Did you have any questions or concerns about the surgery? (Yes / No).

If you answered yes, what were they?

If you answered no, what helped to answer your questions and relieve your concerns?

- **Conversation with Doctor or Nurse**
- **Instructional Video**
- **Instructional Brochure**
- **Other:**

Did the doctor provide educational information to you regarding your condition and surgery? (Yes / No)

If yes what kind?

- **Video**
- **Brochure**
- **Other:**

What helped you make your decision to have surgery?

- **Your Doctor**
- **Spouse**
- **Instructional Information**
- **Second opinion; (from another doctor)**
- **Other:**

Overall, are you satisfied with the result's of the procedure? (Yes / No)

If you're not satisfied, what is the reason for your dissatisfaction?

Did you encounter any difficulty paying for the procedure? (Yes / No)

Are any of your hospital bills being covered by workman's compensation? (Yes / No)

Before surgery how far were you able to walk without resting due to back problems?

Less than 1 block
2 blocks
1 mile
more than 1 mile

Are you a smoker? (Yes / No)

If so how much do you smoke?

Less than 1 pack a day
1 pack a day
2 packs a day
More than 2 packs a day

Were you ever a smoker? (Yes / No) **If you were a smoker, how did you used to smoke?**

Less than 1 pack a day
1 pack a day
2 packs a day
More than 2 packs a day

And, when did you quit smoking?

How would you rate the level of pain you experienced on a typical day before you had back surgery? (1 being No Pain, 6 being severe pain)

1 2 3 4 5 6

What medications did you take for your back before surgery?

How many times per day, week, or month did you usually take this medication? How many pills did you take each time?

What medications do you take now?

How many times per day, week, or month do you usually take this medication? How many pills do you take each time?

How would you rate the level of pain you experience on a typical day now that you have had back surgery? (1 being No Pain, 6 being severe pain)

1 2 3 4 5 6

Did the doctor discuss the possible complications with you? (Yes / No).

Patient Questions

*The following questionnaire is part of a school project for students at WPI. Your responses will be taken into consideration to develop a new patient brochure to spinal surgery.

How many months have you had this condition?

Was this the first spinal fusion surgery you have had? (Yes / No)

Was the injury work related? (Yes / No)

How many times did you meet with the doctor (who performed your back surgery), before the operation?
1 meeting
2 to 3 meetings
4 to 5 meetings
greater than 5

Before your back surgery, how often did your back problem prevent you from doing activities that require strength or flexibility, such as golfing, active sports, heavy housecleaning, gardening, heavy lifting, etc.?
Usually (More than ¾ of the time)
Often (between ½ to ¾ of the time)
Sometimes (between ¼ and ½ of the time)
Rarely (less than ¼ of the time)
Never

Before your back surgery, how often did back pain prevent you from doing light to moderate activities, such as washing dishes, cooking, light cleaning, going up stairs, light lifting, etc.?
Usually (More than ¾ of the time)
Often (between ½ to ¾ of the time)
Sometimes (between ¼ and ½ of the time)
Rarely (less than ¼ of the time)
Never

Before your back surgery, how often did back pain interfere with your social life, that is, visiting friends, eating out, etc.?
Usually (More than ¾ of the time)
Often (between ½ to ¾ of the time)
Sometimes (between ¼ and ½ of the time)
Rarely (less than ¼ of the time)
Never

Questionnaire for Spinal Fusion Patients

<u>Nurse / Physician Response</u>

*****What is the diagnosis of the condition?**

Degenerative Disk Disease Spinal Stenosis Spondylolisthesis

Degenerative Scoliosis Facet Joint Syndrome Other

*****What technique was used to perform the spinal fusion?**

Laparoscopic Minimally invasive open Traditional Open Other

*****How was the spine approached during surgery?**

Anterior Posterior Anterior & Posterior

*****Were fixation device used to stabilize the spine? If so what kind?**

BAK (inter-body fusion cage) Pedicle screw fixation Other:

APPLICATION FOR APPROVAL OF UMMS HUMAN STUDIES
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
UMass/Memorial Health Care

NOTICE TO INVESTIGATOR

Before the HSC meeting deadline, you must submit **ONE COPY** of the completed HSC application, including all 8 of the sections. All signatures and attachments should be in place. **The application and consent form must be numbered.** This packet will be reviewed in the Research Subjects Office and returned to you.

This administrative review is done to prevent receiving applications that are poorly prepared and unacceptable to the Committee. You are urged to prepare this application and consent form carefully. The two Human Subjects Committees review 10-20 protocols a month. The Committees are composed of individuals who donate a considerable amount of their time to this effort. While they are always willing to cooperate in resolving ethical issues that arise regarding research, they resent being asked to review applications that are carelessly prepared, containing typographical errors and obvious mistakes in describing the protocol.

INVESTIGATORS SHOULD PROOF READ THE FINAL VERSION OF THE APPLICATION FORM BEFORE IT IS SUBMITTED. FAILURE TO DO SO WILL PUT YOUR STUDY AT A VERY HIGH RISK OF BEING TABLED UNTIL THE NEXT MEETING.

INSTRUCTIONS

DRUGS OR RADIATION

If the subjects are given any drugs, the Pharmacy and Therapeutics Committee must approve. Please call the Hospital Operator at 856-0011 and ask to have the on call Investigational Pharmacist paged.

If the subjects receive any radiation, the Radiation Safety Committee must approve. Please call Joe Bakanauskas at 856-4901.

SIGNATURES

1. The PI signs Section III the assurance and Section VII the Informational Drug Data Form (IDDF).
2. The Chair of the PI's Department, and the Chief of the PI's Division sign Section IV the Study Approval and Section VII (IDDF).
3. Other faculty Investigators sign Section VI A.
4. Other Department Chairs sign Section VI B.

PROCEDURES FOR SUBMITTING A COMPLETE APPLICATION

If you are unsure about the type of review required by your study or are inexperienced in completing HSC applications, it is strongly recommended that you provide a copy of a reasonably complete draft version for a substantive preliminary review by the Director of Research Subjects before you complete the final version. This preliminary review gives you the opportunity to address issues before the meeting and will save you time in the long run. Obviously, this review must be done well in advance of the HSC meeting deadline.

EXPEDITED REVIEW

If the study qualifies for Expedited Review (determined by the Research Subjects Office after review) the original and three copies of the final version of the application will be required. The protocol will be reviewed by two Committee members. This process usually takes approximately one week.

FULL COMMITTEE REVIEW

If the study must be reviewed by the full Committee, the original and twenty five copies will be needed (one for each member of the Committee). **Please note that the original copy of the full application and consent form must be sent to the Research Subjects Office for initial administrative review before making the twenty five copies for the Committee.**

Meetings are scheduled for the first and third Tuesday of each month at 4:00 P.M.(except for the months of July and August when the Committee meets once each month). Meeting dates, times, submission deadlines (2 weeks before the meeting), and meeting locations are subject to change, please contact the Research Subjects Office at 856-4261 for more information.

Each protocol will be prereviewed by a Committee member before the meeting, and the investigator may be contacted to respond to concerns. You will be notified of the date and location of the meeting. Most Principal Investigators do not have to attend the meeting, but you are asked to be on call via your pager or telephone between the meeting hours of 4-6 p.m.

AMENDMENTS

Any change in a protocol or consent form after its approval must be reviewed by the Committee. No changes may be instituted until the investigator has received written approval of the revision from the Committee.

YEARLY REVIEW AND REAPPROVAL

Approved studies must receive reapproval at least once a year and more often if required by the Committee. A reapproval form will be sent to you before the reapproval is due.

CONTENTS OF THIS APPLICATION

SECTION I
CHECK LIST

Before this application is submitted to the Research Subjects Office, the following must be done. Please indicate by stating **"YES" OR "N/A"** (not applicable) that you have reviewed the packet and have accomplished these tasks as they apply to your study.

IN THE APPLICATION SECTION

_____ Completed Protocol Summary Sheet Section II

_____ Completed & obtained signatures on the P.I.'s Assurance Section III and Department Assurance Section IV.

_____ Obtained signed agreement forms from all cooperating faculty and departments Section VI.

_____ Obtained approval from Radiation Safety Committee or submitted protocol to the RSC.

_____ Completed & obtained signatures on the Informational Drug Data Form Section VII.

_____ Provided the Investigational New Drug Exemption Number (IND #) on the Protocol Summary Sheet Section II.

_____ If this is a Clinical Trial, obtain a Clinical Study Agreement from the Office of Sponsored Programs.

_____ Provided 1 copy of the Company Protocol or the "body" of the research grant (sections A through E of a NIH grant).

_____ Provided 1 copy of the Investigator's Drug Brochure

_____ **Numbered the pages of the Protocol body.**

IN THE CONSENT FORM

_____ Indicated that subjects will sign a written consent form.

_____ Provided a consent form in standard UMMS format Section VIII.

_____ Written the consent form in the second person and at a 7th grade level.

_____ **Numbered the pages of the consent form appropriately. (e.g. Page 1 of 4, Page 2 of 4)**

_____ Indicated that verbal consent will be obtained if written consent is not being obtained.

_____ Provided a fact sheet for the patient in the general format of a consent form for verbal consent process.

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SECTION II

PROTOCOL SUMMARY SHEET
UMASS MEDICAL SCHOOL HUMAN STUDIES APPLICATION
UMass/Memorial Health Care

Today's Date: _____ Department/Division: _____

Principal Investigator: _____

Must be UMMS Faculty Member Last First Degree/Faculty Title Phone/ Pager #

Title:

(Include all titles if protocol covers more than one grant/Include company protocol # and revision date when applicable.)

Primary Contact Responsible for Correspondence: _____

Name Department/Site Phone/Pager#

Identify Condition being studied:

Duration of the project:_____Yrs..

Source of Funds : _
(e.g. NIH, Drug Co.)

Total number of subjects to be studied at UMMS sites per year: _

Drug IND/IDE# Device status(inves./appr.)
(List Below)

Number at each individual UMMS Site:
Clinton : Community Healthlink:

List all cooperating Institutions (not required for national or multicenter studies): _____

Marlborough: Memorial:

University: Other:

DESCRIBE THE RESEARCH BY CHECKING ALL THE ITEMS "YES" OR "NO" WITH AN "X".

YES	NO		YES	NO	
		On Site at UMMS			Medical records/Data banks
		Multicenter Study			Questionnaires
		Cooperating Institutions			Filming/video/audio
		Research Currently funded			Randomization
		Financial interest of investigators?			Placebo
		Funding applied for			Investigational drugs/devices
		UMMS inpatients			Marketed drugs
		UMMS outpatients			Diagnostic Radiation
		Normal volunteers			Therapeutic Radiation
		Other			Chest X-Ray
		Males			Fluoroscopy
		Females			Radioisotopes
		Adults			Has protocol been appr. by Radiation
		Pregnant Women			Safety Committee
		Minors (under 18)			Increased Hospital Costs
		Adolescents (12-18)			**If no, check explanations that apply**
		Infants (under 1 yr.)			No radiation involved
		Fetuses/Abortuses			Would receive radiation regardless of participatior
		Mentally Impaired			Approval Pending
		Prisoners			Date submitted to RSC:

SECTION III
PRINCIPAL INVESTIGATOR'S ASSURANCE

As Principal Investigator for this study, I acknowledge and accept my responsibility, as mandated by the UMMS Assurance of Compliance, for:

•Protecting the rights and welfare of the human subjects taking part in this research study.

•Assuring that the risks to an individual are outweighed by the potential benefits to him/her or by the importance of the knowledge to be gained.

•Complying with all the applicable requirements specified by the UMMS Institutional Review Board as a condition of IRB approval.

•Providing each research subject with a copy of the IRB-approved consent form at the time of consent.

•Retaining the original signed forms in a reasonably secure and confidential area for at least three years after termination of the research project.

•Obtaining approval from the UMMS IRB of any proposed changes in a previously approved study. The proposed changes will not be implemented before IRB review and approval, unless necessary to eliminate apparent immediate hazards to subjects.

•Submitting progress reports of approved research as often as, and in the manner prescribed by, the UMMS IRB (the frequency of these will be on the basis of risk to subjects, but will be at least annually).

•Within five working days report any unanticipated adverse experiences, injuries, and other unanticipated problems that involve risks to subjects and others, either physical, psychological, or threats to privacy.

•Reporting any research subject's death within five working days, regardless of cause.

The Principal Investigator's signature must be obtained before submitting.

Principal Investigator: _____
Signature Date

Type PI name and title:

SECTION IV
DEPARTMENTAL / DIVISIONAL APPROVAL

I have reviewed the attached research project for both ethical considerations and technical merit and recommend it approval.

Department Chair: _____
signature

Type Chair Name and title:

Division Chief: _____
signature

Type Chief Name and title:

SECTION V

DESCRIPTION OF RESEARCH PROJECT

1. PERSONNEL WHO WILL BE ENGAGED IN THE RESEARCH, AND THEIR QUALIFICATIONS (Co Investigators, Research Assistants, etc.)

2. GENERAL STATEMENT OF PROBLEM

a. Purpose: Include concise hypothesis to be tested by proposed research.

3. BACKGROUND AND SIGNIFICANCE: PROVIDE A SUMMARY OF THE FACTS WHICH LED TO SELECTION OF THE PROBLEM; THE INVESTIGATOR'S PREVIOUS WORK ON THE PROBLEM; THOSE ASPECTS THAT JUSTIFY THE USE OF HUMAN SUBJECTS; AND REFERENCES AS APPROPRIATE (USE ADDITIONAL PAPER IF NEEDED).

4. DETAILED DESCRIPTION OF RESEARCH PLAN (especially as it affects the subject)

a. Inclusion/Exclusion Criteria - As appropriate, explain what steps will be taken to insure that subjects meet the criteria, e.g. healthy, not pregnant.

5. PROCEDURES AND METHODS

a. Attach a study schema or flow diagram of the protocol as experienced by the research subjects.

b. Discuss the number of experimental and control subjects, and explain the statistical basis for the numbers.

c. Describe each procedure to be used and include the following information:

1. how long it requires, how often it will be done;

2. doses & route of administration of any drugs;

3. will hospitalization be required for research?

4. whether it would **always**, **sometimes** or **never** be required as part of the subject's standard care.

d. Will there be any material inducements - e.g., direct payment, free hospitalization, care?

YES___ NO___

If yes, explain how much, pay schedule, and any partial payment if subject does not complete study.

e. Disclosure of Conflict of Interest- Investigators should disclose any financial arrangement they may have witl a company whose product figures prominently in their research or financial arrangements they may have with

company making a competing product. **The relationship should also be described in informed consent for human subjects**. In the case where the onlyrelationship is that a company is sponsoring the research st is sufficient to prominently identify the sponsor on the front page of the consent form.

6. RELATIONSHIP TO STANDARD THERAPY.

a. Describe standard therapy that patient would receive if not in the research study. Explain how this research intervention deviates from or replaces generally accepted standard therapy and justify the deviation.

7. DESCRIBE THE POTENTIAL BENEFITS OF THIS PROJECT.

a. Include hoped-for benefit to society, to the group of subjects and to individual subjects. The risk/benefit of the study should be addressed. If there are no direct subject benefits, this should be stated.

8. DESCRIBE THE POTENTIAL RISK TO SUBJECTS INCLUDE PSYCHOLOGICAL, LEGAL OR SOCIAL RISKS AS WELL AS PHYSICAL RISKS.

Include the following information:

a. Estimate likelihood of occurrence, severity, and duration. If generally accepted quantitative estimates are available based on previous data, these should be stated. Otherwise, qualitative estimates such as "rare", "occasionally", "frequently" may be used.

b. Explain what steps will be taken to protect against its occurrence, minimizing the harm, methods for early detection of harm, and what procedures will be followed to avoid serious injury, e.g. withdraw from study or dose reduction.

. Explain whether or not these risks are from a procedure performed with the **intent** and **reasonable prospect** o yielding **direct** health related benefit to subject.

9. CONFIDENTIALITY CONSIDERATIONS: EXPLAIN STEPS THAT WILL BE TAKEN TO INSURE THE CONFIDENTIALITY OF INFORMATION THAT IS OBTAINED IN THE COURSE OF THIS RESEARCH PROJECT. INCLUDE THE FOLLOWING:

a. How will identifiers be used?
b. Where will identifiable data be stored?
c. Who will have access to the identifiable data?
d. When will the data/specimens be destroyed?
e. In the future, might other use be made of specimens collected as part of the research?

10. ECONOMIC CONSIDERATIONS:

a. In the course of this research project, might subject experience any additional expenses as a result of participation? Include both out-of-pocket costs and expenses that might be covered by medical insurance.

YES_____ NO_____ If yes, please explain and justify below.

b. Please explain potential increase in standard hospital cost if any.

11. DESCRIBE THE CHARACTERISTICS OF THE SUBJECT POPULATION.

a. The subject population includes:

ADULTS____CHILDREN _____

b. Is the subject population restricted in respect to any of the following characteristics:

	YES	NO	**("x" as appropriate)**
1. Age Range			
2. Health Status			
3. Gender			
4. Racial/ethnic Composition			

If you responded **YES** to any of the above, please include a clear rationale for this restriction.

12. WILL THE STUDY POPULATION SPECIFICALLY INCLUDE A POPULATION OF SUBJECTS CONSIDERED "VULNERABLE". VULNERABLE POPULATIONS ARE CHILDREN, MENTALLY IMPAIRED, PREGNANT WOMEN, PRISONERS, OR FETUSES.

YES: NO: If yes, please explain.

13. WHAT IS THE SOURCE OF THE SUBJECT POPULATION?

14. EXPLAIN ANY STEPS TAKEN TO INSURE THAT THE SUBJECT POPULATION IS REPRESENTATIVE.

15. HOW WILL SUBJECTS BE RECRUITED FOR THE STUDY? CONSULT THE HSC GUIDELINES FOR THE RESTRICTIONS ON RECRUITMENT OF EMPLOYEES, STUDENTS, AND INPATIENTS.

16. DESCRIBE ANY RECRUITMENT INCENTIVES YOU ARE PLANNING TO OFFER.

17. METHOD FOR OBTAINING INFORMED CONSENT

a. Are you requesting a waiver of the requirement for obtaining consent?

YES: NO: _____

If yes, please justify the request and proceed to Section VI. Consent may be waived if research is minimal risk; the waiver does not adversely affect the subject **and could not practically be carried out without the waiver.** Your justification must address these issues.

18. WILL VERBAL CONSENT BE OBTAINED?

YES: NO:
If yes, will an unsigned "fact sheet" be given to subjects before verbal consent is obtained?

YES: NO:

19. WILL A SIGNED CONSENT FORM BE REQUIRED?

YES: NO: _____

20. AS A GROUP, ARE THESE SUBJECTS EXPECTED TO BE COMPETENT TO GIVE CONSENT FOR THEMSELVES?

YES: NO:

21. DOES SUBJECT POPULATION INCLUDE MINORS? CONSULT HSC GUIDELINES FOR INFORMATION ABOUT CHILDREN IN RESEARCH STUDIES.

YES: NO:

— ———

If yes, will children be given an assent form to sign?YES: NO: _____

NOTE: In general, it is expected that minors from age 12 to 15 will read and sign an assent form. Older adolescents (16 and 17) will usually also read and sign the same consent form their parents sign.

22. EXPLAIN HOW THE MINORS WILL BE APPROACHED TO ASSENT TO PARTICIPATION.

23. IDENTIFY SPECIFIC INDIVIDUALS IN THE PROJECT WHO WILL OBTAIN CONSENT FROM SUBJECTS. (E.G. M.D.s, RESEARCH ASSISTANTS, R.N.s)

24. EXPLAIN THE CIRCUMSTANCES UNDER WHICH CONSENT WILL BE OBTAINED. HOW WILL YOU INSURE THAT POTENTIAL SUBJECTS HAVE ADEQUATE TIME TO CONSIDER THEIR OPTIONS, AND THAT POSSIBLE COERCION IS MINIMAL.

SECTION VI
CERTIFICATION OF APPROVAL

A. CERTIFICATION OF APPROVAL OF PARTICIPATION IN A RESEARCH PROJECT BY UMMS FACULTY MEMBERS.

My signature below indicates that I approve of and agree to participate as a coinvestigator in the following research project.

Project Title: _____

Principal Investigator:_____DEPT.: SITE:

1. Name(please type):_____Dept.:

   Signature:_____Site:

2. Name(please type):_____Dept.:

   Signature:_____Site:

3. Name(please type):_____Dept.:

   Signature:_____Site:

4. Name(please type):_____Dept.:

   Signature:_____Site:

5. Name(please type):_____Dept.:

   Signature:_____Site:

6. Name(please type):_____Dept.:

   Signature:_____Site:

7. Name(please type):_____Dept.:

   Signature:_____Site:

8. Name(please type):_____Dept.:

   Signature:_____Site:

9. Name(please type):_____Dept.:

   Signature:_____Site:

B. CERTIFICATION OF APPROVAL BY A DEPARTMENT CHAIR FOR PARTICIPATION IN A RESEARCH PROJECT CONDUCTED BY A FACULTY MEMBER FROM ANOTHER DEPARTMENT.

This form is to be signed by the Chair of Departments **other than that of the Principal Investigator**. The Chair of the Principal Investigator's Department should sign Section V of the HSC application only.

MY SIGNATURE BELOW INDICATES THAT I AM AWARE OF AND AGREE TO THE PLAN TO INVOLVE MY DEPARTMENT IN THE FOLLOWING RESEARCH PROJECT:

Project Title:
Principal Investigator:_____Department:

THIS RESEARCH WILL INVOLVE:

____ PATIENTS FROM MY DEPARTMENT OR DIVISION WILL SERVE AS A SOURCE OF SUBJECTS.

____ FACULTY FROM MY DEPARTMENT OR DIVISION.

Department Chair's Signature:_____Date:_____

Please type Chair's Name:

Department Name: Site:

SECTION VII
INFORMATIONAL DRUG DATA FORM

DEPARTMENT OF PHARMACY

Docket #:_____

Drug Name or Code No.:

Other Name (s):

Is the drug approved by the FDA? Yes: No:

Protocol Title:

Dosage Form and Strength:

Dose (Approx. Human):_____ Route of Administration:_____ Schedule:

Special Instructions for Administration: _____

Pharmacologic/Therapeutic Properties:

Possible Side Effects:

Precautions:

reatment of Overdose: _____

Literature References: _____

UMMS Source: Pharmacy: Other (Specify):

Storage Requirements:

Principal Investigator:_____Print Name:_____

Co-Investigators:_____

Date Submitted:_____Submitted By:_____

Approved by (Chief of Clinical Department or Service):_____

Reviewed by Investigational Drug Service:_____

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SECTION VIII

HSC CONSENT FORM TEMPLATE AND INSTRUCTION

This template for a consent form is being provided for your assistance. It is impossible to address all the variations that might occur. This form should not be used without careful consideration of how it applies to your own specific protocol and subject population. Adaptation and variation is to be expected. Treatment, and low-risk protocols in particular will need to be revised in many of the areas.

Whenever possible, the wording shown should be used. The consent must be written in language easily understandable to lay people. The consent must be paginated and the docket # must appear at the top of each page. **Only consent forms stamped with the approval of the Human Subjects Committee may be signed by subjects.**

The instructions are italicized and are not supposed to be in the consent form which is submitted to the committee for review. Likewise, any parts that do not apply to your study should be deleted from the form.

The consent form is available on a computer disk in Word 6.0 and WordPerfect 6.1 in the Research Subjects Office.

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UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Title:

Principal Investigator: Date:

Sponsor:

Research Subject's Name:_____Date:

Invitation To Take Part and Introduction
You are invited to volunteer for a research study. You are asked to take part because you...*Explain why subject is being selected to be in the study.*

Purpose of Research
The goal of this research is to see if...*Explain the purpose of the study and briefly describe the disease condition under study. State why this treatment (etc.) might help.*

Your Rights
It is important for you to know that:

- **Your participation is entirely voluntary.**
- **You may decide not to take part or decide to quit the study at any time, without any penalty.**
- **You will be told about any new information or changes in the study that might affect your participation.**

Description of The Experimental Drug/Device *(If applicable)*

Name of the experimental drug or device... has not yet been approved by the U.S. Food and Drug Administration (FDA) for sale by prescription. It has been developed by....Co. and has been tested in animals and in well people (*if applicable*). It is still being tested in people with ..(*condition being studied)* and about (#) patients have been tested so far.

(If applicable)
RANDOMIZATION
Since no one knows yet whether the experimental drug *(drug name)*, will be effective or not, not everyone in the research study will be treated with *(drug name)*. Each volunteer in the study will

get either . . . or a placebo. A placebo is an inactive substance which looks exactly like the experimental drug, but which is not expected to have any medical effects. This means you may

not receive the drug being tested. The decision as to whether you receive the drug or placebo will be made by chance, like the flip of a coin, not by your doctor or based on your medical condition. Neither you nor the doctors will know whether you are getting the experimental drug or a placebo. You have . . . chances in . . . of getting the experimental drug. This way of studying medicines provides more objective information about the drugs and allows better comparisons to be made. In an emergency, a doctor can find out what you are taking by calling 856-0011 and have the operator page the on call Investigational Pharmacist.

PROCEDURES

Briefly describe:

1. The procedure the volunteer will undergo to determine eligibility;

2. How treatment will be administered; how often treatment will be given.

3. The procedures done for the research: blood drawing- include volume of blood in teaspoons (1tsp. = 5cc, 1tbsp. = 15cc); other invasive procedures, neurological tests, questionnaires.

4. The total duration of time required on the part of the volunteer. Specify the number of hospital, clinic, inpatient, or outpatient visits; if volunteer will be hospitalized, for how long. Number of times tests will be repeated; and duration of treatment and follow up.

5. ***Distinguish clearly those procedures that will be done for research purposes only.*** *These include experimental procedures and also routine procedures that would not, or might, not, be part of the individual's' standard care. Likewise, distinguish those procedures that are standard care and would be carried whether or not the subject was in the study.*

Format for the description of procedures is as follows, adapt it to your specific protocol:

Your participation in the research will last up to . . . Years, require a total of . . . Outpatient visits and . . . day stay in the hospital.

You will have the following test to see if you meet the requirements for being in the research study. *List everything that will be done as part of the screening and indicate whether it is or is not part of the standard treatment for this individual.*

This first visit will take about. . .

Next, you will be given a . . . 's supply of either the experimental drug or the placebo, depending on which you were assigned to take. This will be . . . (*e.g. a pill to take four times a day, after each meal and at bedtime.)*

You will have to come to the clinic. . . times according to the following schedule:

Al all of these visits you will have *List everything that will be done at these visits and indicate whether it is or is not part of the standard treatment for this individual.*

These visits will take about. . .

This is *(more often than, or the same as)* your would have to come for check-ups if you were not in the research study.

CONFLICT OF INTEREST DISCLOSURE
Clinical investigators should disclose any financial arrangement they may have with a company whose product figures prominently in their research or financial arrangements they may have with a company making a competing product by describing the relationship. In the case where the only relationship is that a company is sponsoring the research study, it is sufficient to prominently identify the Sponsor on the front page of the consent form.

RISKS
Include as appropriate: ***Description should include all side effects in the protocol and the investigators brochure.*** *The relative rate of occurrence should be stated (either frequently, occasionally, rarely or a % if known. Information about whether the side effects are reversible should be included. If there are many risks the most common side effects should be underlined. Include psychological, legal socioeconomic risk and any inconveniences and discomforts associated with any of the procedures.*

RISKS OF THE INVESTIGATIONAL DRUG/DEVICE
The following side effects of . . .have been reported. The most common side effects are underlined or in bold-face type. Unless otherwise stated, the side effects will go away when the drug is stopped. In addition you may experience other unforeseen side effects that have not been reported before.

RISKS OF THE EXPERIMENTAL PROCEDURES
Explain the most common risks known and potential risks of the experimental procedures. Underline or bold-face type the most common risks.

RISKS OF STANDARD PROCEDURES BEING DONE FOR PURPOSES OF THE RESEARCH WHICH YOU MIGHT NOT NEED TO HAVE IF YOU WERE NOT IN THE STUDY
Explain the risks due to standard procedures which are being carried out only because the subject is in study.

PREGNANCY
Because the safety of *(study drug or device)* during pregnancy and breast feeding is not known, women who are pregnant or nursing may not take part in this study. If you are a woman who is

able to have children, you must have a negative pregnancy test before you begin the study and you must agree to use an effective birth control, such as . . ., during the study. If you become pregnant during the study, you should inform the doctors. You will *explain what will be done if a woman becomes pregnant while in the study.*

Your condition will be watched closely during the study. If you have any serious reactions or problems, the treatment will be changed or stopped to protect your health.

BENEFITS
Select one paragraph that is appropriate for your study.

If the study involves experimental therapy:

It is hoped that the . . .will. . ., however we cannot promise that this will happen.

0r if the study is randomized, placebo controlled:

You may not benefit directly from being in this research study, either because you are assigned to take the placebo, or because the experimental drug does not prove effective. However, your participation may help others with this condition in the future as a result of knowledge gained from the research.
Or if the study is randomized, controlled with an approved treatment drug:

You may not benefit directly form being in this research study, either because you are assigned to take the approved drug which could be prescribed by your doctor even if you were not in the study, or because the experimental drug does not prove effective. However, your participation may help others with this condition in the future as a result of knowledge gained from the research.

Or if the only treatment involved is with an approved treatment drug:

There is no direct benefit to you from being in this study. However, your participation may help others with this condition in the future as a result of knowledge gained from the research.

Or if no treatment is involved and no benefit is anticipated:

There is no direct benefit to you from being in this study. However, your participation may help others with this condition in the future as a result of knowledge gained from the research.

REASONS YOU MIGHT BE WITHDRAWN FROM THE STUDY WITHOUT YOUR CONSENT *As applicable for your study.*

You may be taken out of the research study if:
1. The investigator decides that continuing in the study would be harmful to you.
2. You need treatment not allowed on this study.

3. You fail to keep your appointments or take the medications as instructed.
4. You become pregnant.
5. The study is canceled by the company making the drug, the FDA, or the agency sponsoring the study.

ALTERNATIVES *Select the appropriate paragraph for your study.*

If you decide not to take part in this research study, your treatment would be. . .

or

Other treatments available for your condition include. . . Before you decide to take part in this research study your doctor will give you information and discuss the benefits and risks of these treatments.

COSTS *Select the appropriate paragraph for your study.*

There will be no additional cost to you from being in this research study. The medicines, clinic visits, and tests that are done for research purposes will be free. Any costs for the standard treatment of your condition will be billed to you or your health insurance.

Or if there are procedures done more than once, that might sometimes be billed to subject and at other times paid by the research project.

There will be no additional cost to you from being in this research study. The medicines, clinic visits, and tests that are done for research purposes will be free. Any medical costs for the standard treatment of you condition will be billed to you or your health insurance. The . . . *(e.g. cardiac catheterization)* which is done for research purposes only, will be free, the other . . . will be billed in the usual way. These tests are considered part of standard therapy and are covered by most insurance companies.

CONFIDENTIALITY

Your research records will be confidential to the extent possible by law. In all records of the study you will be identified by a code number and your name will be known only to the researchers. Your name will not be used in any reports or publications of this study. However, the study sponsor, . . ., and the U.S. Food and Drug Administration (FDA) may inspect your medical records that pertain to this research study.

YOUR PARTICIPATION IN THIS PROJECT IS ENTIRELY VOLUNTARY. YOU MAY WITHDRAW FROM THE STUDY AT ANY TIME.

THE QUALITY OF CARE YOU RECEIVE AT THIS HOSPITAL WILL NOT BE AFFECTED IN ANY WAY IF YOU DECIDE NOT TO PARTICIPATE OR IF YOU WITHDRAW FROM THE STUDY.

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RESEARCH INJURY/COMPENSATION *Select the appropriate paragraph for your study.*

If you are injured or have any harmful effects as a direct result of your participation in this research, treatment will be made available to you at University of Massachusetts Medical School (UMMS). If you have health care insurance, the costs associated with this treatment may be billed to your insurer. You will not have to pay any charges resulting from the harmful effect or injury that are not covered by your insurance. If you do not have insurance, you will not have to pay any charges resulting from the harmful effect or injury. This arrangement applies only when

you receive medical care at UMMS. Only necessary medical treatment will be offered to you; you will not receive any additional compensation from UMMS. The fact that UMMS provides this treatment is not an admission by UMMS that it is responsible for the injury.

Or the following statement used when the research project is also considered a treatment. It applies, for the most part, to certain Oncology protocols. You should consult the Research Subjects Office before using it.

If you are injured or have an adverse experience as a direct result of your participation in this research, treatment will be made available to you at the University of Massachusetts Medical School (UMMS). If the treatment is being provided for an unanticipated injury or adverse experience which is not described in this consent form, the cost of this treatment may be billed to your insurer. You will not have to pay any charges that are not covered by your insurance. If you do not have insurance and the treatment is being provided for an unanticipated injury or adverse experience, you will not have to pay any charges resulting from the adverse experience or injury. This arrangement applies only when you receive medical care at UMMS. Only necessary medical treatment will be offered to you; you will not receive any additional compensation form UMMS. The fact that UMMS provides this treatment is not an admission by UMMS that it is responsible for the injury.

If the study sponsor requires a statement related to the sponsor's responsibilities for injury or compensation, this can be added after the UMMS standard statement.

QUESTIONS

Please feel free to ask any questions you may have about the study or about your rights as a research subject. If other questions occur to you later, you may ask Dr. *fill in P.I. name* at *fill in phone number* , the principal investigator. If at any time during or after the study, you would like to discuss the study or your research rights with someone who is not associated with the research study, you may contact the Administrative Coordinator for the Committee for the Protection of Human Subjects in Research at UMMS. The telephone number is (508) 856-4261.

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Pagination should be continuous throughout the consent form but the title, P.I., and subject's name should appear at the top of the page that contains the statement of agreement and the subject's / subject's representative's / witness' signatures.

CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT

Title:

P.I. Name:

Subject's Name:

Below is the standard UMMS Signature paragraph that must be used.

The purpose and procedures of this research project and the predictable discomfort, risks, and benefits that might result have been explained to me. I have been told that unforeseen events may occur. I have had an opportunity to discuss this with the investigator and all of my questions have been answered. I agree to participate as a volunteer in this research project. I understand that I may end my participation at any time. I have been given a copy of this consent form.

_____ Date: _____
Subject's signature

Subject's Representative if appropriate:

Name:_____ Relationship to Subject: _____
(Print)

_____ Date: _____

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Representative's Signature _____

Witness may be used at the P.I.'s discretion

Name: _____
(Print)

Witness Signature:_____ Date: _____

INVESTIGATOR'S DECLARATION

I have explained to the above-named subject the nature and purpose of the procedures described above and the foreseeable risks, discomforts, and benefits that may result. I have asked the subject if any questions have arisen regarding the procedures and have answered these questions to the best of my ability. I have considered and rejected alternative procedures for answering this research question.

This statement may be omitted when it is not appropriate to the study.

I have communicated with Dr. *insert patients attending physician* on *enter date* and in his/her opinion it is acceptable for this patient to participate in this study.

_____ Date:
P.I.'s Signature